UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: BIOPURE SECURITIES LITIGATION	**Civil Action No. 03-12628-NG** **JURY TRIAL DEMANDED** **[Leave to file granted, Docket # 109]**

SECOND CONSOLIDATED AMENDED COMPLAINT

Lead Plaintiff Ronald Erickson and Plaintiffs Stuart Gottlieb, John G. Esposito, Jr., and Emily A. Bittman (collectively referred to herein as "Plaintiffs"), through their attorneys, allege the following upon information and belief, except as to the allegations which pertain to the Plaintiffs and their counsel, which are alleged upon personal knowledge. Plaintiffs' information and belief are based, *inter alia*, on the investigation made by and through his attorneys and on the publicly available information relating to the investigation by the Securities and Exchange Commission ("SEC"), including in particular the SEC's civil fraud complaint (the "SEC Complaint") that was filed in this judicial district on September 14, 2005 in *Securities and Exchange Commission v. Biopure Corporation, Inc., et als.*, No. 05-CA-11853-PBS (the "SEC Action"). A copy of the SEC Complaint is attached hereto as Exhibit A and is incorporated herein, in full, by reference.

INTRODUCTION

1. This is a federal securities class action which is brought by the Plaintiffs against the Defendants, Biopure Corporation ("Biopure" or the "Company") and Biopure's past or present officers and directors, Thomas A. Moore, Carl W. Rausch, Ronald Richards and Howard P. Richman, on behalf of a class (the "Class") consisting of all persons or

entities who acquired the common stock of Biopure during the period April 9, 2003 through December 24, 2003, inclusive (the "Class Period"). Plaintiffs seek to recover damages caused to the Class by Defendants' violations of Sec. 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. This action is also brought under Section 20A of the Exchange Act on behalf of all persons who purchased Biopure common stock contemporaneously with the sales of Biopure's stock by the Defendants Biopure and Rausch (the "Sub-Class") during the Class Period.

2. Biopure develops, manufactures and markets oxygen therapeutics, for both human and veterinary use, designed to serve as an alternative to red blood cell transfusions and for use in the treatment of other critical care conditions. The Company has developed and manufactures two biologic products: Hemopure – 250 (bovine), or HBOC-201 – for human use, and Oxyglobin – hemoglobin glutamer – 200 (bovine), or HBOC-301 – for veterinary use. Oxyglobin is approved for use in the United States for administration to dogs. Hemopure is not approved for *any* human use in the United States; aside from being approved in South Africa for use only in severely anemic surgery patients, it is not approved for human use in any other country.

3. On July 31, 2002, Biopure submitted a biologic license application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking regulatory approval to market Hemopure in the United States for patients undergoing orthopedic surgery (the "Hemopure BLA"). In March 2003, Biopure notified the FDA of its intent to perform Phase III clinical trials of Hemopure on human trauma victims in hospitals.

4. This action arises as a result of the Defendants' issuance of and making of numerous public statements during the Class Period regarding Biopure, Hemopure, the

Hemopure BLA, and Biopure's proposed clinical trials for use of Hemopure for trauma victims (the "Trauma Clinical Trials"). As detailed herein, those statements by the Defendants were false or materially misleading because of the omission therefrom, and because of Defendants' failure to publicly disclose, communications to Biopure from the FDA beginning in April 2003, in which the FDA expressed safety concerns about Hemopure.

5. The FDA's safety concerns arose from adverse event data from Biopure's Phase III orthopedic surgery trial for Hemopure, which adverse event data had been submitted by Biopure to the FDA as part of the Hemopure BLA. As a result of these safety concerns, the FDA placed a clinical hold on the Trauma Clinical Trials on or about April 9, 2003. This action constituted a refusal by the FDA to permit Biopure to conduct its proposed clinical trials for use of Hemopure for trauma victims.

6. In or about May 2003, Biopure's request for the FDA to lift its clinical hold was denied by the FDA.

7. On or about July 30, 2003, the FDA transmitted two long, detailed letters to Biopure conveying still further negative developments with respect to Biopure's efforts at gaining regulatory approval of Hemopure. One letter refused once again to permit Biopure's clinical trials to proceed because of "an unreasonable and significant risk of illness or injury" to human subjects. The other letter constituted FDA's complete response letter to the Hemopure BLA (the "Complete Response Letter").

8. The Complete Response Letter, attached hereto as Exhibit B, informed Biopure that the FDA was not approving the Hemopure BLA due to extensive, significant deficiencies in Biopure's BLA and due to the FDA's persistent, unmitigated concerns about

the lack of safety and efficacy of Hemopure. In the Complete Response Letter, the FDA posed over 200 questions to Biopure. Transmission of the Complete Response Letter signified formally that FDA had completed its review of the Hemopure BLA and that Biopure had a six-month period within which it could resubmit the BLA in a form that addressed all of FDA's concerns.

9. Biopure was never able to address all of the deficiencies, problems, and concerns set forth by the FDA in the Complete Response Letter. Instead, Biopure shifted its focus to developing Hemopure for an entirely different application.

10. The Class Period begins on April 9, 2003, when Biopure first learned of FDA's clinical hold on the Trauma Clinical Trials, due to the FDA's safety concerns about Hemopure, arising from data submitted with the Hemopure BLA. The Class Period ends on December 24, 2003, when Biopure issued a Press Release disclosing the clinical hold and the Defendants' receipt of Wells Notices from the SEC.

11. During all of part of the Class Period, the Defendants concealed from investors the FDA's clinical hold on Hemopure trials, due to the FDA's safety concerns about Hemopure, arising from data submitted with the Hemopure BLA; the FDA's Complete Response Letter; and the true extent and nature of the Hemopure BLA's deficiencies as outlined by the FDA in the Complete Response Letter. Throughout the Class Period, the Defendants spoke optimistically about the prospects for FDA approval of the BLA and falsely and deceptively continued to tout the potential use of Hemopure in the treatment of trauma victims in multiple securities offerings, public filings, press releases, and conference calls for investors. Particularly egregious was Biopure's August 1, 2003 press release, which, just two days after Biopure received the Complete Response Letter, sought to

create the false impression that Biopure had received positive news from the FDA regarding its pending Hemopure BLA. That day, Biopure's publicly traded stock closed at seven dollars and thirty cents ($7.30) per share, a twenty-two percent (22%) increase over its previous day close.

12. The Class Period ends on December 24, 2003. As detailed below, on that date, after the close of trading, Biopure issued a press release (the "December 24, 2003 Press Release") in which it disclosed to the investing public, for the first time, the FDA's communication to Biopure, in April 2003, of the FDA's safety concerns regarding Hemopure and the FDA's imposition of a clinical hold barring the Company from conducting the Trauma Clinical Trials because of those safety concerns. Significantly, in that December 24, 2003 Press Release, it was also disclosed that the Defendants Biopure, Moore and Richman had received a "Wells Notice" from the staff of the SEC which advised those Defendants that the staff of the SEC had preliminarily determined to recommend to the SEC that it bring civil proceedings against them, because, during the time period relevant to this litigation, they had made deceptive statements regarding Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials and they had not disclosed that in April 2003, the FDA had expressed safety concerns about Biopure which led to the imposition by FDA of a clinical hold on the Trauma Clinical Trials.

13. As demonstrated herein, the Defendants' false, misleading and deceptive public statements regarding Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials throughout the Class Period significantly and artificially inflated the price of Biopure stock throughout the Class Period and caused the Plaintiffs and the members of the Class to be damaged.

JURISDICTION AND VENUE

14. This Court has jurisdiction of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. §78aa), and 28 U.S.C. §§1331 and 1337.

15. This action arises under and pursuant to Section 10(b) of the Exchange Act (15 U.S.C. §78j(b)), Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5) and Section 20A of the Exchange Act (15 U.S.C. §78t-1).

16. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. §1391(b). Lead Plaintiff resides in this District, Biopure's principal place of business is located in this District and most of the acts complained of herein occurred in this District.

17. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephonic communications and the facilities of the NASDAQ, a national securities exchange.

PARTIES

18. Lead Plaintiff Ronald Erickson ("Lead Plaintiff") resides in Massachusetts. As detailed in the Certification of the Lead Plaintiff, previously filed in this action (and incorporated herein by reference), the Lead Plaintiff purchased 75,000 shares of Biopure common stock during the Class Period. The Lead Plaintiff did not sell any Biopure common stock during the Class Period.

19. Plaintiff Stuart Gottlieb, as detailed in his Certification previously filed in this action (and incorporated herein by reference) and as detailed herein, purchased shares of Biopure common stock contemporaneously with the sales of Biopure stock by defendants during the Class Period.

20. Plaintiff John G. Esposito, Jr., as detailed in his Certification, previously filed in this action (and incorporated herein by reference) and as detailed herein, purchased shares of Biopure common stock contemporaneously with the sales of Biopure stock by defendants during the Class Period.

21. Plaintiff Emily A. Bittman, as detailed in her Certification previously filed in this action (and incorporated herein by reference) and as detailed herein, purchased shares of Biopure common stock contemporaneously with the sales of Biopure stock by defendants during the Class Period.

22. Defendant Biopure is a Delaware corporation, with its headquarters in Cambridge, Massachusetts.

23. The Defendant Thomas A. Moore ("Moore") was, at all relevant times, Biopure's President and Chief Executive Officer, and a director of Biopure.

24. The Defendant Carl W. Rausch ("Rausch") was, at all relevant times, Biopure's Vice Chairman and Chief Technical Officer, and a director of Biopure.

25. The Defendant Ronald F. Richards ("Richards") was, at all relevant times, Biopure's Chief Financial Officer and Senior Vice President - Business Development.

26. The Defendant Howard P. Richman ("Richman") was, during some of the relevant time period, Biopure's Senior Vice President of Regulatory Affairs and Operations.

27. The Defendant Charles A. Sanders ("Sanders") was, at all relevant times, a director of and Chairman of the Board of Directors of Biopure.

28. The Defendant J. Richard Crout ("Crout") was, at all relevant times, a director of Biopure. Previously, he was a division chief for the FDA.

29. The Defendants Moore, Rausch, Richards, Richman, Sanders and Crout are hereinafter sometimes collectively referred to as the "Individual Defendants."

30. The Defendants Biopure, Moore, Rausch, Richards, Richman, Sanders and Crout are hereinafter sometimes collectively referred to as the "Defendants."

BACKGROUND

Background Information Regarding the FDA

31. The FDA is an agency within the United States Department of Health and Human Services ("HHS") and is responsible for promoting public health by promptly and efficiently reviewing drug approval applications and clinical research, by taking appropriate regulatory action on the marketing of regulated products in a timely manner, and by ensuring that human drugs and devices are safe and effective.

32. The Center for Biologics Evaluation and Research ("CBER") is a center within the FDA that is charged with regulation of biologics (like Hemopure) intended for human use. Biologics are products derived from living sources (in the case of Hemopure, from cows). By contrast, drugs typically are chemically synthesized.

33. The FDA relies on CBER to issue the licenses it requires of companies which manufacture biologics for introduction into interstate commerce. The process for obtaining such a license involves several steps: (1) the manufacturer conducts initial laboratory and animal testing, which do not require prior FDA approval; (2) the manufacturer submits an

investigational new drug application ("INDA") to the FDA seeking permission to conduct human clinical trials concerning a particular indication; (3) after conducting clinical trials, the manufacturer submits the BLA to FDA seeking approval of the biologic; and (4) the FDA reviews the BLA, evaluating the manufacturer's scientific and clinical data and determining whether the biologic meets FDA standards.

34. At all times relevant, the FDA's performance goals and procedures, which were adopted in connection with the Prescription Drug User Fee Act of 1992 ("PDUFA") provided the FDA with ten months in which to review a BLA, subject only to a 90-day extension if the BLA applicant submitted a major amendment within the last three months of the review period. At the expiration of this review period, the FDA must either approve the biologic product for marketing (if it met the FDA's approval standards) or issue a complete response letter which specified the problems with, or deficiencies in, the application.

35. Generally speaking, the issuance of a complete response letter is a significant negative development with respect to the chances of approval for any BLA. The BLA applicant is able to make a further submission in an effort to address the FDA's concerns by answering all questions and addressing all deficiencies set forth in the complete response letter. However, for all non-minor resubmissions, the PDUFA performance goals and procedures specify that FDA has an additional six months within which to reply.

Background Information Regarding Biopure

36. Biopure manufactures only two products. One is Hemopure, which is Biopure's brand name for hemoglobin glutamer - 250 (bovine), an oxygen therapeutic product that is derived from cow's blood and that is intended to act as a substitute to red

blood cells in delivering oxygen to tissues in human beings. The other is Oxyglobin, an oxygen therapeutic created solely for veterinary use.

37. To date, the FDA has not approved the use of Hemopure in human beings for any indication. The only country in the world that has approved Hemopure for use in human beings is South Africa, which has only approved it for use in extremely anemic surgery patients.

38. From Biopure's perspective, gaining FDA approval of Hemopure is absolutely crucial to the continued viability of the Company. Since its founding in 1984, Biopure has devoted substantially all of its resources to the research, development, and manufacturing of Hemopure. Biopure has never been profitable and had an accumulated deficit of over $380 million as of October 2002 and over $425 million in October 2003.

39. The following statements, from Management's Discussion and Analysis of Financial Condition and Results of Operations, January 31, 2003, filed by Biopure with the SEC on March 17, 2003 in its quarterly report on Form 10-Q for the Quarterly Period ended January 31, 2003 (the "January 2003 10-Q"), summarize Biopure's history as follows:

> Since its founding in 1984, Biopure has been primarily a research and development company focused on developing Hemopure, our oxygen therapeutic for human use, and obtaining regulatory approval in the United States. Our research and development expenses have been devoted to basic research, product development, process development, pre-clinical studies, clinical trials and filing a BLA with the FDA....
>
> * * *
>
> Biopure is a leading developer, manufacturer and supplier of pharmaceuticals called oxygen therapeutics. Using our patented and proprietary technology, we have developed and manufacture two products. Hemopure is a first-in-class product for human use that is approved in South Africa for the

> treatment of acutely anemic surgical patients as an alternative to red blood cell transfusion. On July 31, 2002, we submitted a biologic license application (BLA) to the FDA seeking regulatory approval to market Hemopure in the United States for a similar indication in patients undergoing orthopedic surgery....
>
> * * *
>
> Since inception, we have devoted substantially all of our resources to our research and development programs and manufacturing. We have been dependent upon funding from debt and equity financing, strategic alliances and interest income. We have not been profitable since inception and had an accumulated deficit of $392,713,000 as of January 31, 2003. We expect to incur additional operating losses over the next several years in connection with clinical trials, preparation of a marketing application for Hemopure in Europe and other markets and pre-marketing expenditures for Hemopure....
>
> * * *
>
> The completed Phase III orthopedic surgery trial cost approximately $37,000,000 over the four years from protocol development to final report. These trial costs include costs incurred at nearly 50 hospitals, trial site monitoring, data management, regulatory consulting, statistical analysis, medical writing and clinical materials and supplies as well as Company personnel engaged in these activities. Costs incurred in filing the BLA include Company personnel and payments to third parties for manufacturing process documentation, medical consultants, regulatory consultants, integrating the safety and efficacy data bases for all clinical trials and pre-clinical studies. Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation....

January 2003 10-Q, at 8, 10 - 11.

Background Information Regarding the Hemopure BLA

40. On July 31, 2002, Biopure submitted the Hemopure BLA to the FDA, seeking regulatory approval for the use and sale of Hemopure in the United States for anemic patients undergoing orthopedic surgery. For Hemopure to receive such approval, Biopure was required to demonstrate to the FDA that clinical trials of Hemopure had established both its safety and its efficacy. Under the PDUFA goals and procedures, the FDA had until approximately the end of May 2003 in which to complete its review of the Hemopure BLA and either issue an approval letter or a complete response letter.

41. As part of the Hemopure BLA, Biopure submitted to the FDA data from the Phase III clinical trials which it had conducted for the use of Hemopure for patients undergoing orthopedic surgery, including adverse event data.

42. In a letter to Company shareholders dated February 4, 2003, which was included within Biopure's fiscal 2002 Annual Report, Defendant Moore discussed Biopure's priorities while touting the filing of the Hemopure BLA. Declaring that the Company "realized a tremendous achievement" by filing the Hemopure BLA, Defendant Moore stated that Biopure "anticipate[s] that the [FDA] will complete its review of our BLA by mid 2003." The letter also sets forth the Company's "Business Strategy," which included bullet points concerning the Hemopure BLA ("[s]uccessfully launch Hemopure under an orthopedic surgery indication in the United States") and the Trauma Clinical Trials ("[c]linically develop Hemopure for trauma, ischemia, and adjunctive cancer therapy indications"). Beneath the heading "Changing Gears for the Future," Defendant Moore wrote about Biopure's development of Hemopure for use in trauma victims, stating, "Our first clinical priority is to demonstrate the product's utility in stabilizing trauma patients in the emergency room and pre-hospital, or ambulance, setting."

43. In September, 2002, Biopure received a grant from the United States Department of the Army for the purpose of conducting clinical trials of Hemopure for the treatment of certain trauma patients. In Biopure's Annual Report for its fiscal year 2002, filed with the SEC on Form 10-K on January 29, 2003, the Defendants said: **"The Company has identified trauma as its next clinical development priority and is working with a committee of independent civilian and military trauma experts to broaden its trauma program."** (Emphasis added.)

44. In light of the history and the nature of Biopure's business, the most critical and material information about Biopure during the Class Period was the status of the Hemopure BLA, including all facts which bore on when the FDA would rule on the Hemopure BLA and the likelihood that the FDA would (or would not) approve the BLA, thereby approving (or not approving) Biopure's sale of Hemopure in the United States for use with orthopedic surgery patients. Accordingly, information regarding the Trauma Clinical Trials, and particularly the FDA's views and position that the Trauma Clinical Trials would not be allowed to go forward due to the FDA's safety concerns about Hemopure arising from data submitted with the Hemopure BLA, was highly material information regarding Biopure throughout the Class Period.

SUBSTANTIVE ALLEGATIONS

FDA Communicates to Biopure on April 9, 2003 that It Had Imposed A Clinical Hold on Biopure's Trauma Clinical Trials

45. On or about March 7, 2003, Biopure submitted an INDA to the FDA seeking permission to conduct the Trauma Clinical Trials. Biopure supported this submission by relying upon, and referring to, clinical trial data previously submitted in support of its then-pending Hemopure BLA.

46. On or about April 9, 2003, FDA staff members contacted Defendant Richman, Biopure's primary contact person with the FDA, by telephone concerning the INDA. They informed him that FDA was imposing a clinical hold, barring Biopure from initiating any clinical trials connected with the trauma INDA, due to the "safety concerns" arising from data related to the BLA clinical trials and based upon "a preliminary assessment of the BLA." In particular, the FDA staff members expressly referred to data concerning serious adverse events that were experienced by BLA clinical trial participants, and stated that **"the trial was on hold for safety and that in FDA's judgment it is unsafe to put this product in this patient population at this time."**

47. **Thus, as of April 9, 2003, the FDA had advised Biopure that it had placed a clinical hold on their proposed clinical trial of Hemopure for the treatment of trauma patients due to safety concerns arising from the FDA's review of adverse event data from the Company's orthopedic surgery clinical trial, which had been submitted as part of the Hemopure BLA.**

48. Although not on the April 9, 2003 telephone call with the FDA, Defendant Moore learned of the clinical hold the next day, April 10, 2003.

49. These communications in April 2003 from the FDA to the Defendants, were highly material adverse information about Biopure, which would have significantly affected the total mix of information available to an investor in Biopure common stock and which any reasonable investor would have wanted to know in making an investment decision regarding the Company.

50. The FDA's safety concerns, as expressed on April 9, 2003, put Defendants on notice that FDA approval of the Hemopure BLA, a prerequisite to the first commercial

distribution of Hemopure in the United States, was in jeopardy and serious doubt and that the FDA's decision would, unquestionably, be delayed beyond the time frames previously communicated by Defendants to the investing public. Nevertheless, over the next nine months, throughout the Class Period, Defendants intentionally failed to disclose any of these adverse material facts to the investing public - despite numerous opportunities to do so in press releases, analyst conferences and conference calls, and SEC filings. Instead, as detailed below, the Company's periodic statements during the Class Period regarding the Hemopure BLA and the Trauma Clinical Trials were false, deceptive, and fraudulent, and they materially misled investors concerning the status of the Hemopure BLA and the status of the Trauma Clinical Trials.

Biopure Issued Materially False and Misleading Statements to Class Members during the Class Period which Failed to Disclose the Clinical Hold or Its Effect on the Hemopure BLA

51. Throughout the Class Period, the Defendants repeatedly issued and made statements to the investing public and to Class Members about Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials. These statements were contained in Biopure's filings with the SEC; in press releases issued by Biopure (some of which contained direct statements by the Defendant Moore); and in presentations and telephone conferences by Moore and other Individual Defendants to securities analysts, investment advisors and other members of the investing public.

52. As demonstrated and detailed below, the Defendants' statements to Class Members regarding Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials were false, deceptive and misleading because of the Defendants' fraudulent failure to

disclose the FDA's safety concerns. Some of the Defendants' false, deceptive and misleading statements are detailed below.

Biopure Knowingly and Repeatedly Made False and Deceptive Statements in Its SEC Filings and Registration Statements which followed the FDA's April 9, 2003 Communication to Biopure of the Clinical Hold on the Trauma Clinical Trials

53. In numerous SEC filings which followed the April 9, 2003 disclosure to Biopure of the FDA's clinical hold, the Defendants, while purporting to disclose risks faced by Biopure and its shareholders, knowingly and repeatedly made false and deceptive statements regarding its Phase III Hemopure clinical trial. For example, in the Post-Effective Amendment No. 2 to Form S-3 registration statement filed with the SEC on April 11, 2003 (the "April 11, 2003 Registration Statement Amendment"), the Company stated as follows:

> *If We Fail to Obtain FDA Approval We Cannot Market Hemopure in the United States*
>
> We will not be able to market Hemopure in the United States until we receive FDA approval. We have filed an application for approval with the FDA, and the application was accepted for review on October 1, 2002. **We believe that our completed pivotal Phase III clinical trials are consistent with the FDA's most recent guidance on** the design and efficacy and **safety endpoints required for approval of products such as Hemopure for use in surgical indications.**[1] (Emphasis added.)

[1] After making that false and misleading statement, the Defendants added this "proviso:"

> However, the FDA could change its view, require a change in study design or require additional data or even further clinical trials, including trials for indications other than those for which the pending applications seeks approval, prior to approval of Hemopure. The FDA could refuse to grant a marketing authorization. Trials are expensive and time-consuming. Obtaining FDA approval generally takes years and consumes substantial capital resources with no assurance of ultimate success.

54. The statement quoted in the preceding paragraph, from the April 11, 2003 Registration Statement Amendment, including the portion of the quotation in the footnote, is hereinafter referred to as the "False and Deceptive Statement Regarding '*If We Fail to Obtain FDA Approval*.'"

55. The False and Deceptive Statement Regarding '*If We Fail to Obtain FDA Approval*' was false, deceptive and misleading in light of the FDA's safety concerns regarding Hemopure, which the Defendants failed to disclose to Class Members.

56. During the Class Period, the Defendants filed several registration statements with the SEC, in each of which the Defendants repeated the False and Deceptive Statement Regarding "*If We Fail to Obtain FDA Approval,*" nearly or fully *verbatim*, and each of which contained the specific false statement emphasized in the above quoted False and Deceptive Statement Regarding "*If We Fail to Obtain FDA Approval.*" Those registration statements were false, deceptive and misleading because of the Defendants' failure to amend this statement, to disclose the FDA's safety concerns, and to disclose the fact that FDA had as of April 9, 2003 communicated to Biopure that those safety concerns resulted in FDA's placing a clinical hold on the Trauma Clinical Trials. Those registration statements filed within the Class Period, all of which were signed by all of the Individual Defendants (except Richman), included the following:

a. April 11, 2003 Registration Statement Amendment;

b. Post-Effective Amendment No. 1 to Form S-3 registration statement filed with the SEC on April 16 2003;

c. Form S-3 Registration Statement filed with the SEC on June 19, 2003; and

d. Amendment No. 1 to Form S-3 registration statement filed with the SEC on July 2, 2003.

57. The April 11, 2003 Registration Statement Amendment also contained the following misleading and deceptive statements concerning the Company's Hemopure BLA:

> Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation. These BLA support costs were $2,232,000 for the first fiscal quarter of 2003 and are expected to continue at approximately the same level ***until the middle of this calendar year, when the Company is hopeful that it will receive action by the FDA on the BLA.***
>
> * * *
>
> ***If the FDA were to grant marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004.*** We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure... . (Emphasis added.)

58. The April 11, 2003 Registration Statement Amendment was signed by Defendants Richards, Moore, Sanders, Rausch, Crout, and Biopure.

Biopure Begins Raising Money Through Stock Sales to Class Members Without Disclosing the FDA's Clinical Hold

59. On or about April 16 - 17, 2003, after being informed by FDA of the clinical hold on the Trauma Clinical Trials, Biopure filed with the SEC a Post-Effective Amendment No. 1 to a Form S-3 Registration Statement that had been filed in March 2003 and Rule 424(b)(3) prospectus supplements (together, the "April 2003 Offering Documents") for the sale of up to 1 million shares of common stock and warrants for the purchase of up to

500,000 shares of common stock. Defendant Moore substantially participated in the drafting of the April 2003 Offering Documents, which he signed. Defendant Richman reviewed the disclosures contained therein regarding the status of Biopure's FDA submissions, including the Hemopure BLA.

60. In the April 2003 Offering Documents, Biopure stated, *inter alia*:

> We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication
>
> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its periopoerative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. To do so, we will have to design additional clinical trials, submit the trial designs to FDA for review and complete those trials successfully....
>
> * * *
>
> The Company expects to initiate additional pre-clinical and clinical trials this year to expand the indications for Hemopure beyond surgery.
>
> * * *
>
> We are also developing Hemopure for potential use in trauma and other medical applications.

61. Biopure's April 2003 Offering Documents were false and misleading because they misled investors about the true status of the Hemopure BLA and the Trauma Clinical Trials, given the fact that FDA had by that point in time instituted a clinical hold on the Trauma Clinical Trials. In particular, the April 2003 Offering Documents were false and misleading to investors in four key respects. First, the April 2003 Offering Documents falsely stated that Biopure had only applied for an indication involving Hemopure's

perioperative use in orthopedic surgery patients, when in actuality Biopure had also sought permission to conduct the Trauma Clinical Trials. Second, though they discussed the potential use of Hemopure in trauma victims, the April 2003 Offering Documents failed to disclose that the FDA had instituted its clinical hold on the Trauma Clinical Trials due to safety concerns which arose from the FDA's preliminary assessment of the Hemopure BLA. Third, the April 2003 Offering Documents disclosed a future "expectation" to expand Hemopure's indications and to design and submit additional trials for FDA review at a time when Biopure had already designed additional clinical trials (the Trauma Clinical Trials), submitted the trial designs for FDA review, and been notified that FDA instituted a clinical hold. Fourth, the April 2003 Offering Documents referred to development plans for the trauma indication without disclosing the clinical hold placed on the Trauma Clinical Trials due to the FDA's safety concerns.

62. On April 24, 2003, Biopure and Moore issued a press release which stated, *inter alia*:

> CAMBRIDGE, Mass., April 24/PRNewswire-FirstCall/ – Biopure Corporation (Nasdaq: BPUR) has appointed Ketchum to provide public relations support and LifeBrands to provide medical education support for Biopure's investigational oxygen therapeutic, Hemopure®...
>
> The U.S. Food and Drug Administration is currently reviewing Biopure's biologic license application "BLA" to market Hemopure in the United States. Ketchum and LifeBrands will provide communications support for Hemopure and handle educational activities surrounding the anticipated product introduction in orthopedic surgery and the clinical development of other potential indications in trauma, ischemia and cancer.
>
> "We look forward to successful partnerships with Ketchum and LifeBrands as we prepare to commercialize this first-in-class product," **said Thomas A. Moore, President and Chief Executive Officer of Biopure. "Based on our interactions**

> **with the FDA and the guidelines in the Prescription Drug Users Fee Act, we're hopeful the agency will complete its review of our marketing application mid-year."**
>
> Biopure is seeking FDA approval to market Hemopure for the treatment of acutely anemic adult patients undergoing orthopedic surgery, and for the purpose of eliminating or reducing the need for red blood cell transfusions in these patients. As part of the BLA review process, the FDA has completed its inspections of Biopure's manufacturing and data-handling facilities and has audited its contract research partners and several clinical sites in the United States and South Africa. Biopure has responded to all questions raised by the FDA during the inspections and has resolved all previous manufacturing documentation issues with the FDA. Hemopure continues to be manufactured and is available for shipment. (Emphasis added.)

63. The April 24, 2003 Press Release was false and misleading due to Defendants' failure to disclose in it the FDA's clinical hold on the Trauma Clinical Trials and the FDA's reasons therefore.

FDA Confirms The Clinical Hold in Writing and Informs Biopure of Serious Safety Concerns Arising from the Pending Hemopure BLA

64. On or about April 25, 2003, the FDA sent a letter (the "April 25, 2003 FDA Letter") to Biopure that was addressed to Defendant Richman, in which it confirmed that a clinical hold had been placed on the Trauma Clinical Trials sought by Biopure's INDA because "subjects would be exposed to an unreasonable and significant risk of injury." The April 25, 2003 FDA Letter reiterated that the clinical hold was predicated on safety concerns which arose from the FDA's preliminary assessment of the Hemopure BLA. Specifically, the FDA stated, "[R]esults of a pivotal human trial, used in support of the Hemopure BLA, and referred to in the IND[A], indicated that use of Hemopure, compared to human blood, was associated with a higher incidence of life-threatening SAE's [Serious Adverse Events],

including death and cardiac arrest." Defendants Moore and Richman received a copy of the April 25, 2003 FDA Letter at the latest by April 30, 2003.

Biopure Continues to Raise Money from Stock Sales Without Disclosing the Clinical Hold or FDA's Serious Safety Concerns Arising from the Pending Hemopure BLA

65. On or about May 6, 2003, Biopure filed with the SEC two documents (together the "May 2003 Prospectus Supplements"): (1) a Rule 424(b)(3) prospectus supplement to the April 2003 Offering Documents dated May 2, 2003 and (2) a Rule 424(b)(3) prospectus supplement to the April 2003 Offering Documents dated May 5, 2003. The May 2003 Prospectus Supplements incorporated by reference certain of Biopure's prior public filings (including prior offering documents and periodic reports) and, taken together, provided for the sale of up to 1,715,687 shares of common stock and warrants to purchase up to 343,138 shares of common stock. Defendant Moore substantially participated in the drafting, review, and/or approval of the May 2003 Prospectus Supplements. Defendant Richman reviewed the disclosures contained therein regarding the regulatory status of Biopure's FDA submissions, including the Hemopure BLA.

66. The May 2003 Prospectus Supplements were false and misleading because they failed to disclose that FDA had implemented a clinical hold barring the Trauma Clinical Trials from proceeding due to safety concerns which arose out of FDA's preliminary assessment of the Hemopure BLA. They were further misleading insofar as they incorporated by reference, rather than amending, the false and misleading statements and omissions contained in the April 2003 Offering Documents.

Biopure Unsuccessfully Petitions the FDA to Lift the Clinical Hold While Continuing to Raise Money from Stock Sales Without Disclosing the Clinical Hold or FDA's Serious Safety Concerns Arising from the Pending Hemopure BLA

67. On May 12, 2003, in response to the FDA's clinical hold on the Trauma Clinical Trials, Biopure made an extensive submission to the FDA requesting that the hold be lifted. Termed a "complete response" to the FDA's April 25, 2003 FDA Letter, the submission was signed by Defendant Richman, who, along with Defendant Moore, participated in its drafting and review.

68. On or about May 14, 2003, Biopure filed a Form 8-K with the SEC ("May 2003 Form 8-K"), which Defendant Moore reviewed and approved before filing. It attached as an exhibit a Standby Equity Distribution Agreement dated April 16, 2003 between Biopure and BNY Capital Markets, Inc. ("BNYCMI"), under which Biopure could issue and sell up to $10 million of class A common stock periodically through BNYCMI, as Biopure's exclusive agent for the offer and sale of the shares. The May 2003 Form 8-K disclosed certain of the agreement's terms, including Biopure's representation and warranty that the Company's registration statements and prospectuses:

> ...conformed and will conform in all material respects to the requirements of the Exchange Act and the rules and regulations of the [Securities and Exchange] Commission promulgated thereunder, and none of such documents contained or will contain at such time an untrue statement of a material fact or omitted or will omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

69. The May 14, 2003 May 2003 Form 8-K was false and misleading because, as discussed herein, both the April 2003 Offering Documents and the May 2003 Prospectus Supplements contained untrue statements of material fact and/or omitted to state material

facts necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

70. On May 22, 2003, Biopure issued a press release announcing its Q2 results for fiscal 2003 ("May 22, 2003 Press Release") and included the text of the release in a Form 8-K filed with the SEC ("May 2003 Form 8-K"). Defendants Moore and Richman each substantially participated in the drafting, review, and/or approval of the May 22, 2003 Press Release.

71. The May 22, 2003 Press Release contained a section entitled "Recent Corporate Events" which listed, *inter alia*, a statement referring to the Trauma Clinical Trials ("Biopure is preparing for a Phase 2a in-hospital trauma trial."). This was misleading because Biopure omitted to state that the FDA had instituted a clinical hold on the Trauma Clinical Trials due to safety concerns that arose from its preliminary assessment of the Hemopure BLA. In addition, the May 22, 2003 Press Release made the following misleading and deceptive statements regarding the Hemopure BLA and the Trauma Clinical Trials:

> Based upon FDA performance goals and guidelines in the Prescription Drug User Fee Act (PUDFA), **Biopure is hopeful that in mid 2003 the FDA will complete its review and act on Biopure's biologic license application (BLA) to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery.** As part of this review, the agency has inspected the company's manufacturing and data-handling facilities and has audited its contract research partners and several clinical sites in the United States and South Africa. **Biopure has responded to all questions raised by the FDA to date.** (Emphasis added).
>
> The U.S. Army has notified Biopure that the company will receive approximately $4 million in FY03 Congressional funding, in addition to a $908,900 grant previously awarded in FY02 [footnote omitted], designated to fund trauma trials of

> Hemopure in emergency rooms and ambulances. In addition, in March 2003 Biopure and the Naval Medical Research Center (NMRC) signed a collaborative research and development agreement (CRADA) to help fund and conduct a pivotal trauma trial of Hemopure. Participation in this collaborative effort is estimated to cost the NMRC at least $4 million. Biopure will contribute an estimated $8.7 million, of which at least $643,000 will be provided during the first year. Biopure is preparing for a Phase IIa in-hospital trauma trial, and the study protocols for Phase Iib/pivotal pre-hospital trial are currently under scientific review by the NMRC.

72. On May 22, 2003, the Defendants Biopure, Moore, Richards and Richman participated in a telephonic conference call for analysts and institutional investors (the "May 22, 2003 Investor Call"). As described below, a live audio webcast of the conference call was available to all members of the investing public. A copy of the transcript of that conference call, prepared by CCBN StreetEvents, for Biopure, is attached hereto as Exhibit C, and incorporated herein by reference.

73. During the May 22, 2003 Investor Call, the Defendants made statements and answered questions from public participants, about Biopure, the Hemopure BLA and the Trauma Clinical Trials, which were false, deceptive and misleading. For example, the Defendant Moore made the following false, deceptive and misleading statements during the May 22 Conference Call:

> a. "...we continue to be very hopeful of an [FDA] response on our [biologic] license application by mid-year or sooner, and **we continue to not be aware of any major issues with that application at this time....**"
>
> b. "On FDA I'll just reiterate, I guess, at our last quarter we ... had answered all FDA questions and **we were unaware of any major issues. Fundamentally we're in the same place now.**"

> c. **"We continue to say we are not aware of anything that would cause undue delay** [in receiving a response from the FDA to the Hemopure BLA]..."
>
> d. "**Our aim will be to have the product**, again, assuming we get approved, **on or about June 1st** to the end business [sic] **and moving product no later than October 1st**."
>
> e. "**Parkman Hospital is going to be our initial clinical center to conduct the already announced in-hospital trauma trials** that will set us up for the subsequent pre-Hospital trials to establish an additional trauma indication for Hemopure."

(Exhibit C at 1 and 2, emphasis added).

74. The May 22, 2003 Investor Call was false and misleading because Defendants Moore and Richman misrepresented the true information that Biopure had received from the FDA in several ways. First, the statement that "we continue to not be aware of any major issues with that application at this time" was false and misleading because the FDA had already informed Biopure about serious safety concerns from the clinical trial information submitted in support of the Hemopure BLA, which had resulted in the FDA's imposing a clinical hold on the Trauma Clinical Trials. Second, the reference to Parkman Hospital as being Biopure's "initial clinical center to conduct the already announced in-hospital trauma trials" was misleading because it failed to disclose that the FDA's clinical hold barred those trials from taking place. Third, it was misleading to tout the potential for using Hemopure in trauma victims at all because doing so failed to disclose that FDA had instituted a clinical hold based upon safety concerns which arose based on FDA's preliminary assessment of the Hemopure BLA.

75. Those statements were made directly by the Defendants Moore, Richman, and Biopure, but they also constituted statements by Defendant Richards, in light of the fact

that, while participating in the May 22, 2003 Investor Call, he acquiesced in and did not, in any way, correct those statements which he knew to be false, deceptive and misleading.

76. All of the statements made by the Defendants during the May 22, 2003 Investor Call were available to all members of the investing public. Specifically, as stated in the May 23, 2003 Press Release:

> Biopure President and CEO Thomas A. Moore will host a conference call at 4:30 p.m. EDT on Thursday, May 22, 2003, to briefly review the company's activities and financial position. The dial-in numbers for analysts and institutional investors are 1-800-387-5428 (US/Canada) and 1-706-634-1328 (International).
>
> A live webcast of the conference call will be available from the investors section of Biopure's web site at www.biopure.com and will be archived for 30 days. The webcast can also be heard by individual investors at www.companyboardroom.com and by institutional investors who subscribe to StreetEvents at www.streetevents.com. An audio replay of the conference call will be available from approximately 7:30 p.m. EDT, May 22, 2003, until midnight May 30, 2003. To access the replay, dial 1-800-642-1687 (US/Canada) or 1-706-645-9291 (International/Local) and Reference Conference ID number 438897.

Biopure's Submission Fails to Persuade the FDA to Lift the Clinical Hold on the Trauma Clinical Trials

77. On or about May 30, 2003, the FDA sent two letters to Biopure ("May 30, 2003 FDA Letters"), addressed to Defendant Richman, in response to Biopure's May 12, 2003 request that the clinical hold on the Trauma Clinical Trials be lifted. In one letter, the FDA stated that Biopure's request contained serious inconsistencies and failed to address any of FDA's safety concerns which prompted the clinical hold. Also, **the FDA informed Biopure that, with respect to Hemopure, its "conclusions about product safety**

remain unchanged." Further, the FDA required Biopure to conduct "at least three additional studies in conscious swine" to address particular concerns before any human testing could occur. In the other letter, the FDA told Biopure that it was extending the deadline to complete its review of the Hemopure BLA for 90 days - until August 29, 2003 - because Biopure's May 12, 2003 request to lift the clinical hold contained significant new analyses of the Hemopure clinical data and therefore constituted a "major amendment" to the Hemopure BLA.

78. Defendants Moore and Richman received copies of both of the May 30, 2003 FDA Letters on our about May 30, 2003.

Biopure Disseminated False Reasons for the FDA's 90-Day Extension, which It Misleadingly Characterizes as Positive News for the Hemopure BLA

79. On May 30, 2003, after receiving both of the May 30, 2003 FDA Letters, Biopure issued a press release (the "May 30, 2003 Press Release") announcing that the FDA had notified Biopure that it had extended the time for it to act on the Hemopure BLA for an additional 90 days, until August 29, 2003. Defendants Moore and Richman substantially participated in the drafting, review and approval of the May 30, 2003 Press Release. In it, Biopure explained the FDA's action as follows:

> Biopure submitted its BLA on July 31, 2002. Under FDA performance goals in the Prescription Drug User Fee Act (PDUFA III), the agency has up to 10 months from the submission date to review and act on the BLA, making the original action due date June 1, 2003. As part of the normal review process, Biopure has responded to FDA questions regarding the application. The agency has classified the latest responses submitted in mid-May 2003 as additional analyses of previously submitted data, which under FDA standard operating procedures automatically provides the agency up to three months beyond the original action due date to review the data. This type of action is not unusual–the last 11 standard

> BLAs accepted for review by the FDA have undergone a 13-month review.

80. In the May 30, 2003 Press Release, the Defendant Moore made the following statement regarding the FDA's action:

> "We're very pleased with the FDA's progress in reviewing our application," said Biopure President and CEO Thomas A. Moore. "We continue to work closely with the agency toward a final decision that will allow us to make Hemopure available as an alternative to red blood cell transfusion. We're also continuing our preparations to roll out the product to leading orthopedic surgery centers following approval."

81. The May 30, 2003 Press Release was false and misleading in several ways about the true information that Biopure had received from the FDA. First, it falsely stated that Biopure had responded to the FDA regarding the Hemopure BLA, when in actuality the Company had responded to questions about the trauma INDA and the clinical hold, which it had still not disclosed. Second, it falsely stated that Biopure's submission was "part of the normal review process" of the Hemopure BLA and constituted Biopure's "latest responses" to FDA questions about the Hemopure BLA when in actuality the submission was the Company's "complete response" to the April 25, 2003 FDA Letter and was submitted for the sole purpose of trying to persuade the FDA to lift the clinical hold. Third, the May 30, 2003 Press Release failed to disclose, *inter alia*, that the FDA had placed the trauma INDA on clinical hold due to safety concerns over the data submitted in support of the Hemopure BLA, that the 90-day extension imposed by FDA was the result of Biopure's request to lift the clinical hold, and that the FDA had refused to lift the clinical hold even after the Company had made a substantial submission to FDA requesting that the hold be lifted.

82. In the May 30, 2003 Press Release, Biopure also announced that it would hold a conference call on May 30, 2003 at 3 pm ET, at which it "will discuss the regulatory status of Hemopure..." (hereinafter, the "May 30, 2003 Investor Call"). Like the May 22, 2003 Investor Call, analysts and institutional investors could participate and all members of the investing public could hear the call live and access it thereafter for a period of time. A copy of the transcript of the May 30 Conference Call, entitled *Biopure Corporation Conference Call to Discuss the Regulatory Status of Hemopure*, prepared by CCBN StreetEvents, for Biopure, is attached hereto as Exhibit D, and incorporated herein by reference.

83. The Defendants Moore, Richman and Richards participated in the May 30, 2003 Investor Call on behalf of Biopure. Defendant Moore made the following false, deceptive, and misleading statements which were intended to falsely characterize the 90-day extension imposed by the FDA as a positive development:

> We view this notification [of the 90-day extension] as a very positive development for Hemopure. First of all, we have a date which the agency has indicated their intent to give us an action letter. Second, it confirms what we already knew, that is, that the agency has devoted considerable effort to this application. And third, as we also already knew, that now our investor community knows, there is nothing in our application which is warranted a denial of that application at the three key decision points we've passed so far in the PDUFA process. By that, I mean our BLA was accepted, it was also continued through the mid-cycle review conducted by the agency, and now, at the PDUFA guideline date for a first response, we've not had a denial, but rather a going forward to additional consideration. The added time we're going to get over the next three months will not only allow us to insure we can fully answer additional questions the FDA might choose to send our way, but also allow us to complete legal negotiations and to continue forward with the commercial preparations we are making against a hopeful approval on August 29th for the name of introducing this product on or about the October

> introductory guideline we mentioned in our conference call last week. So we feel very positive about this....

(Exhibit D at 1-2).

84. As reflected in the transcript, the analysts participating in the May 30, 2003 Investor Call expressed concern about the fact that the FDA had extended the time for it to act on the Hemopure BLA for an additional 90 days, until August 29, 2003. They asked pointed questions regarding the reasons for that delay by the FDA, to which the Defendants gave false, deceptive and misleading responses. Some of that colloquy was as follows:

> **Sapna Srivastava** - *Think Equity - Analyst*
>
> [D]id the FDA request any additional data to be submitted, or why do you think that basically the FDA extended the time line for the review process?
>
> **Thomas A. Moore** – *Biopure - CEO and President*
>
> The FDA did not request any additional data. . . .
>
> **Howard P. Richman** - *Biopure - SVP Regulatory Affairs & Operations*
>
> . . . This is what normally happens with any submission. As Tom has told the public over the past many months, is that we are in continued dialogue with the agency and during that period of time, they have requested information which we have sent back to them. It's a normal process with any application. Be that as it may, the agency, during the course of reviewing the information has the opportunity to take additional time to allow them to give a complete and additional thorough review of all information to make a thorough conclusion on application. This type of response from the FDA is very common with biologic licensing applications. ...
>
> * * *
>
> **Richard Adams** - *Bennett Lawrence - Analyst*
>
> ...why are you still having to provide information to the FDA? You said mid-May there was a resubmission of some sort.

Why nine and a half months after the original BLA was submitted are you still having to provide information?

Thomas A. Moore – *Biopure - CEO and President*

...This mid-May submission was some additional analysis which we provided on data that was already in the BLA. At the time, we didn't consider it a major amendment to the BLA but the FDA looked at that as a reason to extend it...

Howard P. Richman - *Biopure - SVP Regulatory Affairs & Operations*

. . . Just as a point of clarification this is a normal occurrence. I've been lucky to be involved with 12 other approval processes outside of Biopure and this is a normal thing that happens. We're, in fact, in constant contact with the agency when they're requesting information in real time. So this is not anything new that can happen. And what we have done is supply responses back to their continual questions to allow them, again, as I mentioned earlier, to give complete and thorough response to this first in class application.

Richard Adams – *Bennet Lawrence - Analyst*

...but it would seem that for there to be some sort of submission that would extend the PDUFA date another two months, it would have to be something material. And I guess I'm just surprised that nothing was disclosed in mid-May when this additional submission was made.

Thomas A. Moore – *Biopure - CEO and President*

To be clear, we were simply responding to a new set of questions from FDA. It did not involve any new data. And so frankly, it was well within the range of other questions we've answered in the past. When we made that response, we didn't characterize it as a major amendment to the BLA...

*** * ***

Gabe Hoffman - *Occipital Capital - Analyst*

...Could you please be a little more specific in terms of – the company has submitted additional analyses of previously

submitted data. Could you be a little more specific as to what elements of the clinical data that that refers to?

Thomas A. Moore – *Biopure - CEO and President*

I can't be a lot more specific.

Gabe Hoffman – *Occipital Capital - Analyst*

I mean, is it safety, is it statistical procedure, is it some auditing of patient records? I mean, could you just be somewhat more specific?

Thomas A. Moore – *Biopure - CEO and President*

Well, all patient records have been audited and so all that's been done, so that's not at issue as far as I know anyway.

Gabe Hoffman – *Occipital Capital - Analyst*

Or merely is it formatting or you know?

Thomas A. Moore – *Biopure - CEO and President*

It's actually – it was a dialogue really about how to look at the clinical data. As you know, there are various analyses used to look at our efficacy and safety data and we just had a dialogue about the different ways you could look at the analyses that are performed on the data. And that's really as far as I want to characterize it.

Gabe Hoffman - *Occipital Capital - Analyst*

But could you just give us maybe a broader ballpark sense as to – you know, just a broad area that it is – is there a specific area that it's in that's a broad area that maybe you could characterize it? That's more specific than just it's the clinical data?

Thomas A. Moore – *Biopure - CEO and President*

Well, I mean, all the clinical data has to do with safety and efficacy. That's the only thing in measure in these clinicals. And so, the dialogue is over those clinical and safety and efficacy data. And again, we have answered some questions on a pretty broad basis. When I talk about it as how to look at

> the clinical analysis, it's exactly what it was. So I think that's as far and as specific as I really want to be at this point.
>
> * * *
>
> **Roberto McNuln** - *Bridger Capital - Analyst*
>
> To get some more information about the additional data asked for – given your assessment that the questions asked were very broad, I'm still unclear as to why then at this late in the date it would require a three month delay. I would understand if the questions were very detailed that the FDA would ask for – would take that additional time. But your assessment of the questions being very broad makes me want to get some more detail about that.
>
> **Thomas A. Moore** – *Biopure - CEO and President*
>
> ...the FDA chose to look at this as a major amendment to the BLA...if we submit new information about any aspect of the product or new analysis about any aspect of the product, whether it's pivotal to their decision or not, they can decide that that's a reason to go for the extension. So I'm not sure whether or not the data we submitted, we did not submit any new data, whether that was a reason for the extension of whether the echo simply needed an extension, period.

(Exhibit D at 2-5 and 7).

85. The May 30, 2003 Investor Call, including those statements, was false, deceptive and misleading in light of the FDA's safety concerns, the clinical hold imposed on the Trauma Clinical Trials after a preliminary assessment of the Hemopure BLA, and the impact of both on the Hemopure BLA - all of which the Defendants failed to disclose. Further, Defendants falsely optimistically characterized the 90-day extension as part of a normal, ongoing dialogue with FDA about the Hemopure BLA when in actuality it was necessitated by Biopure's submission seeking to address the FDA's safety concerns and lift the clinical hold. Those statements were made directly by the Defendants Moore, Richman, and Biopure, and they also constituted statements by Defendant Richards, in

light of the fact that, while participating in the May 30, 2003 Investor Call, he acquiesced in and did not, in any way, correct those statements which he knew to be false, deceptive and misleading.

Biopure Continues to Conceal the Clinical Hold from the Public in Periodic Reports and Offering Documents Filed with the SEC

86. On or about June 16, 2003, Biopure filed its quarterly report on Form 10-Q with the SEC for the quarter end April 30, 2003 (the "April 2003 10-Q"). Defendant Moore substantially participated in the drafting, review and/or approval of the non-financial reporting sections, and Defendant Richman reviewed disclosures regarding the regulatory status of Biopure's submissions to the FDA. The April 2003 10-Q contained the False and Deceptive Statement Regarding "*If We Fail to Obtain FDA Approval*" and the following false and deceptive statement:

> ***If the FDA grants marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004.*** We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure... . (Emphasis added.)

April 2003 10-Q, at 16.

87. The April 2003 10-Q was signed by the Defendant Richards. Furthermore, as required by SEC Rules 13a-14(a) and (b) and 15d-14(a) and (b), promulgated pursuant to the Exchange Act, the April 2003 10-Q contained certifications by the Defendant Moore, as the Chief Executive Officer of Biopure and the Defendant Richards, as the Chief Financial Officer of Biopure, in which they each certified:

> 1. I have reviewed this quarterly report on Form 10-Q of Biopure Corporation;

and in which they then falsely certified:

> 2. Based on my knowledge, **this quarterly report does not** contain any untrue statement of a material fact or **omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading** with respect to the period covered by this quarterly report; [emphasis added]

Id., at 35 - 36.

88. The Defendants Moore and Richards also certified that Biopure and they had designed "disclosure controls and procedures" which would have ensured that they would have learned of any FDA safety concerns, so they could have been timely and properly disclosed to the investing public in the April 2003 10-Q. Specifically, Moore and Richards certified that:

> 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a - 14 and 15d -14)[2] for the registrant and we have:
>
> a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during

[2] Exchange Act Rules 13a - 14(c) and 15d -14(c) define "disclosure controls and procedures" as follows:

> ...controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. **Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive officer or officers and principal financial officer or officers...** (Emphasis added.)

> the period in which this quarterly report is being prepared;
>
> b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
>
> c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date...

Id., at 35-36.

89. The "conclusions about the effectiveness of the disclosure controls and procedures" referenced in the above quoted certification by Moore and Richards, set forth in the April 2003 10-Q, were as follows:

> (a) Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) within 90 days of the filing date of this Quarterly Report on Form 10-Q (the "Evaluation Date"). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded as of the Evaluation Date that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Id., at 22.

90. On or about June 19, 2003, Biopure filed a Form S-3 registration statement and prospectus and on or about July 2, 2003, Biopure filed a Pre-effective Amendment No. 1 for Form S-3 registration statement and prospectus with the SEC for the sale of common stock and warrants for the purchase of common stock (together, the "Summer 2003

Registration"). On or about July 3, 2003, Biopure filed a Rule 424(b)(3) prospectus with the SEC for the sale of common stock and warrants for the purchase of common stock ("July 2003 Prospectus"). Defendant Moore signed the Summer 2003 Registration and substantially participated in the drafting, review and approval of both it and the July 2003 Prospectus. Defendant Richman reviewed the disclosures concerning the regulatory status of the Company's FDA submissions.

91. The April 2003 10-Q, the Summer 2003 Registration, and the July 2003 Prospectus were all false and misleading with respect to the true status of Biopure's Trauma Clinical Trials. These documents failed to disclose the FDA clinical hold which barred Biopure from conducting the Trauma Clinical Trials due to safety concerns identified after a preliminary assessment of the Hemopure BLA. They were misleading in stating that the "only" application applied for was an indication involving Hemopure's perioperative use in orthopedic surgery when in actuality Biopure had also applied for permission to conduct the Trauma Clinical Trials. They were also misleading by discussing a future "expectation" to expand Hemopure's indications and to design additional trials and to submit them to FDA for review when in actuality Biopure had already designed additional trials (the Trauma Clinical Trials), submitted their designs to FDA, and received a clinical hold due to safety concerns.

Biopure Unsuccessfully Petitions the FDA Again to Lift the Clinical Hold on the Trauma Clinical Trials While Continuing to Raise Money from Stock Sales Without Disclosing the Clinical Hold or FDA's Serious Safety Concerns Arising from the Pending Hemopure BLA

92. On or about July 2, 2003, Biopure made a submission to the FDA, in response to the May 30, 2003 FDA Letters, in yet another attempt at having the clinical hold lifted. Defendant Richman prepared and signed this submission at the direction of Defendant Moore, who reviewed it before it was sent to the FDA.

93. On or about July 17, 2003, Biopure filed a Form 8-K with the SEC ("July 2003 Form 8-K"), which was reviewed and approved by Defendant Moore prior to filing. The July 2003 Form 8-K attached as an exhibit a "Placement Agency Agreement," dated July 17, 2003, between Biopure and ThinkEquity Partners, LLC ("TEP"), pursuant to which TEP was to act as exclusive placement agent for the Company in its sale of up to $17.22 million of class A common stock. Among the terms of the agreement with TEP that were disclosed in the July 2003 Form 8-K was Biopure's representation and warranty that its registration statements and prospectuses:

> ...conformed and will conform in all material respects to the requirements of the Exchange Act and the rules and regulations of the [Securities and Exchange] Commission promulgated thereunder, and none of such documents contained or will contain at such time an untrue statement of a material fact or omitted or will omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

94. The July 2003 Form 8-K was false and misleading because, *inter alia*, Biopure's prior SEC filings themselves contained untrue statements of material fact or omitted to state material facts necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

95. On or about July 18, 2003, Biopure filed a Rule 424(b)(5) prospectus supplement to the July 2003 Prospectus for the sale of up to 3,083,000 common stock shares to institutional investors (the "July 2003 Offering Document"). It incorporated by reference certain of the Company's prior public filings, including offering documents and periodic reports. Defendant Moore substantially participated in the drafting, review, and/or approval of the July 2003 Offering Document. Defendant Richman reviewed disclosures concerning the regulatory status of Biopure's FDA submissions.

96. The July 2003 Offering Document was false and misleading because, *inter alia*, it failed to disclose the FDA's clinical hold on the Trauma Clinical Trials due to safety concerns that had arisen during the preliminary review of the Hemopure BLA and because it incorporated by reference prior filings (discussed herein) which likewise contained false statements and omissions.

97. On July 23, 2003, Biopure issued a press release announcing that it had raised $17.2 million in gross proceeds through the sale of 3,083,000 shares of its common stock at $5.58 per share.

The FDA Refuses to Approve Hemopure, Issues Biopure a Complete Response Letter to the Hemopure BLA, and Refuses to Lift the Clinical Hold on the Trauma Clinical Trials

98. On July 30, 2003, Biopure received two highly significant letters from the FDA. One was a letter once again refusing to lift the clinical hold on the Trauma Clinical Trials (the "July 30, 2003 Trauma Clinical Trials Letter"). It was received by Defendants Moore and Richman on or about July 30, 2003 and about which Biopure's General Counsel was made aware no later than July 31, 2003. The other was FDA's Complete Response Letter (the "Complete Response Letter"), Exhibit B hereto, in which FDA informed Biopure

that its Hemopure BLA was not approved due to the FDA's safety concerns about Hemopure arising from data submitted with the Hemopure BLA. Defendants Moore and Richman and Biopure's General Counsel all received copies of the Complete Response Letter on or about July 30, 2003.

99. From July 30, 2003 until December 11, 2003, Defendants continued to mislead investors through numerous public filings, press releases, and statements, by failing to disclose Biopure's receipt of the FDA's Complete Response Letter (despite the fact that FDA staff and Biopure's own outside regulatory counsel repeatedly and consistently identified the letter to Defendants as being a "complete response letter"), by misrepresenting the nature and extent of the deficiencies in the Hemopure BLA raised by the FDA, and by failing to disclose the continued existence of the FDA's clinical hold on the Trauma Clinical Trials, as well as FDA's refusal to lift the hold despite repeated requests by Biopure that it do so.

100. The Complete Response Letter's opening sentences set forth the FDA's unambiguous rejection of the Hemopure BLA, stating:

> The Center for Biologics Evaluation and Research (CBER) has completed the review of all submissions made relating to your Biologics License Application. **Our review finds that the information and data submitted are inadequate for final approval action at this time because on the deficiencies outlined below**.

Exhibit B at 1 (emphasis added).

101. The Complete Response letter also summarized the numerous deficiencies which the FDA found in Biopure's Hemopure BLA - a process which took the FDA **34 single-spaced pages** to accomplish. See Exhibit B. Altogether, the Complete Response Letter contained over **220** individual deficiencies and questions concerning Biopure's

clinical trials and data submitted in support of the Hemopure BLA and concerning the safety and efficacy of Hemopure. Id.

102. The most significant deficiencies and questions raised in the FDA's Complete Response Letter concerned the conduct of Biopure's clinical trials and the integrity of the data, in particular the following: (1) whether adequate controls had been used to ensure that the data underlying Biopure's Hemopure BLA was sufficiently accurate and reliable to form the basis for conclusions by the FDA about Hemopure's safety and efficacy, and (2) why Biopure had failed to perform certain analyses that the FDA had expected and recommended be performed. In addition, the FDA expressly reserved the right to re-evaluate Hemopure's safety and efficacy pending the resolution, if any, of the data integrity issues it brought to Biopure's attention in the Complete Response Letter.

103. The Complete Response Letter also stated that the review clock regarding Hemopure was suspended as of its issuance. In essence, the FDA informed Biopure via the Complete Response Letter that it was taking no further action on the Hemopure BLA unless and until Biopure could resolve to its satisfaction all of the 220 deficiencies that FDA raised concerning the Hemopure BLA.

104. In the July 30, 2003 Trauma Clinical Trials Letter, the FDA once again refused to lift the clinical hold it had placed on the Trauma Clinical Trials because, in the FDA's words, **"human subjects are or would be exposed to an unreasonable and significant risk of illness or injury."** In support of that conclusion, the FDA cited many of the same deficiencies, questions, and concerns raised in the Complete Response Letter regarding the Hemopure BLA, the adequacy of controls concerning Biopure's prior Hemopure clinical trials and the analysis of the resulting data, and the safety of Hemopure.

105. The importance of Biopure's receipt, on July 30, 2003, of the Complete Response Letter and the July 30, 2003 Trauma Clinical Trials Letter cannot be overstated. The letters were lengthy, detailed, and together spelled out an insurmountable array of deficiencies in the Hemopure BLA which essentially signaled the death knell for Biopure's chances of **ever** gaining FDA approval for Hemopure. This defeat was especially pronounced given that as of July 30, 2003, Biopure had made two substantial submissions to the FDA requesting that it lift the clinical hold on the Trauma Clinical Trials, each of which failed to adequately address the FDA's safety concerns.

106. On or about the morning of July 31, 2003, Defendant Richman telephoned an FDA staff member working on the Hemopure BLA and the INDA for the Trauma Clinical Trials to discuss what steps Biopure should take following receipt of the Complete Response Letter. That staff member identified the letter as in fact being a "complete response letter" and told Defendant Richman that Biopure could, within 10 days of its receipt, take one of four possible actions: (1) amend the Hemopure BLA, (2) notify the FDA of its intent to amend the Hemopure BLA, (3) withdraw the Hemopure BLA, or (4) request a hearing. Defendant Richman asked whether Biopure could take 30 days to respond to the Complete Response letter, since it had been issued 30 days before its due date. The FDA staff member responded by saying that the Complete Response Letter stopped the review clock, no further FDA review would occur until Biopure responded to all 220 deficiencies outlined in the Complete Response Letter, that a partial response would not be considered, and that once FDA received Biopure's response to the Complete Response Letter, the FDA would have a new review cycle of six months to review it.

107. On or about July 31, 2003, Biopure, through its General Counsel, contacted outside legal counsel specializing in FDA regulatory matters to discuss the Complete Response Letter and a press release Biopure intended to issue. The draft press release stated that Biopure had received correspondence from the FDA, but did not identify it as being a "complete response letter." Outside counsel orally advised Biopure's General Counsel that he "didn't have time to read letter but looked like complete response [sic]," that the draft press release looked "unduly optimistic," and that issuance of the Complete Response Letter "30 days early in this context while true isn't great cause optimism [sic]." Biopure's General Counsel informed Defendants Moore and Richman of the substance of these comments by outside counsel.

Biopure Misleads the Public About the FDA's Complete Response Letter and the July 30, 2003 Trauma Clinical Trials Letter

108. On August 1, 2003, Biopure issued a press release (the "August 1, 2003 Press Release") in which it disclosed that the FDA was seeking additional information in connection with the Hemopure BLA and that the FDA had suspended its review clock on the Hemopure BLA. Defendants Moore and Richman substantially participated in the drafting, review and/or approval of the August 1, 2003 Press Release.

109. Specifically, the August 1 Press Release said:

> CAMBRIDGE, Mass., Aug. 1, 2003 /PRNewswire-FirstCall via COMTEX/ – Biopure Corporation (BPUR) announced today that the U.S. Food and Drug Administration (FDA) has completed its review of the company's biologic license application (BLA) for Hemopure® [hemoglobin Glutamer - 250 (bovine)] and issued a letter requesting additional information. The letter focuses primarily on clarification of clinical and preclinical data and includes some comments on labeling. It does not request additional clinical trials. Biopure has applied to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery

> and for the elimination or reduction of red blood cell transfusions in these patients.
>
> With 30 days remaining in the original BLA review cycle, the issuance of the letter has suspended the FDA review clock until Biopure submits a complete response.
>
> "We're encouraged that the FDA has finished its review and provided comprehensive feedback in advance of the formal action due date. By maintaining thirty days on the review clock, the FDA is encouraging us to work with them to complete the approval process as quickly as possible," said Biopure President and CEO Thomas A. Moore. "We'll work with the Agency to address the remaining questions and will provide our answers as expeditiously as possible."

110. The August 1, 2003 Press Release was false, deceptive and misleading to investors in its portrayal of the information that Biopure had received from the FDA. First, the August 1, 2003 Press Release failed to disclose altogether Biopure's receipt of the Complete Response Letter from the FDA. Second, its tone was deceptively and inaccurately optimistic, notwithstanding the fact that Biopure had just received two detailed letters from the FDA that together constituted a tremendous, if not insurmountable, setback in the Company's efforts at ever gaining FDA approval of Hemopure. Defendant Moore's statement that the FDA's letter was "encouraging" Biopure to "complete the approval process as quickly as possible" was misleading insofar as it had no basis in fact and was inconsistent both with the gravity and number (220) of deficiencies outlined in the Complete Response Letter and with the time it would take the Company to respond. Third, the August 1, 2003 Press Release's reference to the 30 days remaining in the review cycle was misleading, because the FDA had a six-month time frame within which to respond, if and when the Company actually responded to all of the deficiencies outlined in the Complete Response Letter. Fourth, the August 1, 2003 Press Release was misleading by stating that

FDA had not requested additional clinical trials when in actuality FDA had questioned the integrity of the Company's submitted data (a preliminary step in determining whether new clinical trials were necessary) and implemented a clinical hold, which it refused to lift, barring the Trauma Clinical Trials from occurring. In fact, the August 1, 2003 Press Release failed to disclose any information about the clinical hold, including that it had been implemented; that the Company had twice tried and twice failed to persuade FDA to lift it; and that the FDA, on July 30, 2003, had sent the detailed July 30, 2003 Clinical Trials Letter refusing (again) to lift it and identifying many of the same deficiencies, concerns, and questions outlined in the Complete Response Letter.

111. The text of the August 1, 2003 Press Release was included in a Form 8-K that Biopure filed with the SEC (the "August 1, 2003 Form 8-K"), which was therefore false and misleading for the same reasons. The August 1, 2003 Press Release, by itself and through its inclusion within the August 1, 2003 Form 8-K, artificially inflated the price of Biopure's common stock.

112. The August 1, 2003 Press Release was issued on the morning of August 1, 2003. The marketplace, not knowing of its false and misleading nature, strongly and positively responded to the August 1, 2003 Press Release. On August 1, 2003, the price of Biopure common stock closed at $7.30 per share, up $1.33 per share, or 22.27%, over its close at $5.97 per share on July 31, 2003. Biopure's stock traded as high as $9.03 per share on August 1, 2003, on volume of almost 7 million shares.

113. On or about August 5, 2003 Biopure's General Counsel sent an e-mail message to outside counsel specializing in FDA regulatory matters requesting help in formulating a strategy for responding to the Complete Response Letter. In a reply e-mail

sent the same day, the Company's outside counsel identified the July 30, 2003 letter as being a "complete response letter."

114. Thereafter, the price of Biopure stock continued to rise, closing on August 20, 2003 at $8.12 per share.

Biopure Continues to Misrepresent the Complete Response Letter and to Conceal the Existence of the Clinical Hold on the Trauma Clinical Trials

115. On August 31, 2003, Biopure issued a press release announcing its Q3 financial results for fiscal year 2003 ("August 21, 2003 Press Release"). Defendants Moore and Richman participated in the drafting, review, and/or approval of the August 21, 2003 Press Release.

116. The August 21, 2003 Press Release included the following statements concerning the FDA's review of Biopure's Hemopure BLA:

> On July 30th, the FDA sent Biopure a letter stating that the agency has completed its review of the company's BLA to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The letter requests additional information and suspends the BLA review clock with 30 days remaining in the original review cycle. It does not request additional clinical trials. Biopure is preparing its response, which, when submitted, will restart the review clock. "We've developed many of our initial responses and so far we feel we will be prepared to answer FDA's questions," said Moore. "We have an opportunity to answer all of the Agency's remaining questions before it acts on our application, so we want to be sure we're fully meeting the FDA's needs. Therefore, we are requesting a meeting with the FDA in September. The Agency is allowing Biopure to set the agenda for this meeting, which will enable us to request any clarifications we need to complete our responses. The timing for when we'll submit our complete response to the FDA will be driven by the guidance we receive during this meeting."

117. The August 21, 2003 Press Release was false and misleading to investors about the true information that Biopure had received from the FDA. First, it failed to disclose that the Company had received a Complete Response Letter from the FDA. Second, its references to 30 days remaining in the review cycle were misleading about the true six-month time frame within which the FDA could respond to Biopure, if and when the Company first responded to all 220 deficiencies outlined in the Complete Response Letter. Third, the August 21, 2003 Press Release was misleading by stating that the FDA had not requested additional clinical trials, when in actuality the FDA was questioning the integrity of the Company's clinical data previously submitted in support of the Hemopure BLA (a preliminary step to determining whether additional clinical trials were necessary) and was refusing to lift the clinical hold barring conduct of the Trauma Clinical Trials. Fourth, the August 21, 2003 Press Release failed to disclose any information whatsoever about the clinical hold, including that it had been implemented; that the Company had twice tried and twice failed to persuade FDA to lift it; and that the FDA on July 30, 2003 had sent the detailed July 30, 2003 Clinical Trials Letter refusing (again) to lift it and identifying many of the same deficiencies, concerns, and questions outlined in the Complete Response Letter.

118. The text of the August 21, 2003 Press Release was included in a Form 8-K that was dated September 15, 2003 and filed with the SEC ("September 15, 2003 Form 8-K"). By including without amendment the text of the August 21, 2003 Press Release, the September 15, 2003 Form 8-K was false and misleading for the same reasons as articulated above.

119. Also on August 21, 2003, the Defendants Biopure, Moore, Richards, and Richman participated in a telephonic conference call for analysts and institutional investors (the "August 21, 2003 Investor Call"). Like the May 22, 2003 Investor Call, analysts and institutional investors could participate in the August 21, 2003 Investor Call and all members of the investing public could hear the call live and access it thereafter for a period of time. A copy of the transcript of that conference call, prepared by CCBN StreetEvents, for Biopure, is attached hereto as Exhibit E and incorporated herein by reference.

120. During the August 21, 2003 Investor Call, Defendants made statements and answered questions from public participants, about Biopure, the Hemopure BLA and the Trauma Clinical Trials, which were false, deceptive and misleading. For example, Defendants made the following statements:

> **Thomas A. Moore** – *Biopure - CEO*
>
> The agency has done us a big favor by providing what amounts to a complete detailed response and set of questions to Biopure prior to the end of the review cycle, and then stopping the review clock with 30 days remaining in the PDUFA cycle. They have thereby made a commitment to give us an action letter 30 days after we provide our response to their questions. They could just as easily have announced an end to the review cycle with their response, in which case they would have had two to six months to respond to our answers instead of the 30 day period.
>
> * * *
>
> Our efforts to date suggest that we're in good shape so far to be able to answer FDA's questions.
>
> * * *
>
> **Jason Colbert** - *Susquehanna Capital - Analyst*
>
> . . . A couple of questions on the letter from the FDA. You used the term complete response a couple of times. But, this isn't a complete response letter. What is it exactly?

Thomas A. Moore – *Biopure - CEO*

It's, and I'll ask Howard Richman to comment on this in just a second. It is – I think Howard will call it a hybrid, and by that I mean it genuinely represents all the questions that FDA would like to have us answer, and so in that sense it's like a complete response. But normally a complete response letter brings an end to the review cycle. And the agency has elected not to do that, offering us this precious opportunity to get a response 30 days after we submit the answers to those questions. And so, that's what it is.

Jason Colbert - *Susquehanna Capital - Analyst*

It sounds like the response is going to take some time. Can you tell me about how many questions are involved? And the followup question is, depending on the length of your response, is it reasonable to expect that the FDA is going to be able to respond back within that 30 day timeline? If you give them a very exhaustive detailed response back, as I know you will, isn't it going to take the FDA longer than 30 days to respond back?

Thomas A. Moore – *Biopure - CEO*

I think that's a very fair question, and that's one of the motivations we have for having a meeting with FDA simply so we can agree on how we're going to order this data and maybe how we can share some of the data as we go so that it makes it easier for them to meet that guideline.

Howard P. Richman - *Biopure - SVP Regulatory Affairs & Operations*

I'll share this with yourself and for the other people listening. This type of letter is very unique. As Tom clearly stated for everyone, it is a hybrid, it's something that was done from the (indiscernible) perspective to work with Biopure in this aspect because you're right in stating that people have (indiscernible), this does not follow the area that we've seen where you look on FDA sites or in other complete responses. This was done with the specific intent to work with us. With that being said, it counts in such a way that they want us to be able to get back to them vis-a-vis this meeting and in our answers. Many of our answers will not be that detailed in response, some in clarification, which will only meet the FDA with some points

we're going to discuss with them. Other ones will just provide them information they requested in terms of clarification and follow-up source documents and other information they've asked about. So when you say about a detailed (indiscernible) response, in many ways it will not be. But it's also clear that the formation that they have for us with FDA which will be clarified on a meeting in September will clearly enlighten us and them and give a clear pathway to the response in a correct time frame.

* * *

Richard Adams - *Bennett Lawrence - Analyst*

Just to repeat a question from earlier that I didn't hear an answer to which was the number of questions in the FDA letter. Can you tell us that?

Thomas A. Moore – *Biopure - CEO*

We probably aren't going to disclose that. I guess I shouldn't say probably. The number of questions isn't going to do very helpful to people to understand what's really in the letter. ... What I will say is there's probably about 50 substantive questions which we have - - which we're working on which are really the core of the efforts that we're doing now. So, I think the number 50 is more useful to bear in mind that the list... .

* * *

Alan Ferguson – *3i Technology Partners - Analyst*

Is there anything on the work the trials that the military is doing in trauma yet?

Thomas A. Moore – *Biopure - CEO*

We've not initiated human clinical trials in trauma with the military or for that matter on the civilian side as yet. So, we hope to get started on that ASAP. I think probably those trials will begin, however, at least after we have – no sooner than after we filed our responses with FDA on the BLA questions. As I mentioned earlier in my flurry of discussions about meetings, Naval medical research has been very active in doing preclinical work on trauma with our product, and then sharing those results in several different forms actually. So,

> work is going on very actively on the trauma side, but I don't believe human trials will begin until after we have completed our answers to the BLA. Part of this is related to the fact that we already are engaged in FDA in a dialogue on a total clinical development program in trauma with FDA. And so we expect the final discussion on that with FDA will ensue after we've addressed the questions they've asked for us on the use in anemia from surgery indications.
>
> * * *
>
> **Richard Aussie** - *Nation Direct - Analyst*
>
> . . . My question is, what will you do if Biopure doesn't get FDA approval?
>
> **Thomas A. Moore** – *Biopure - CEO*
>
> . . . While we are continuing to be cautiously optimistic, we're on the approval track. If you ask us to specifically address this question, which you have, I guess what I'd say is the FDA doesn't really just say no. At least not in a situation like this where an application has been accepted and taken this far down the review track. What the FDA says is here's what you've got to do, guys, if you want to persuade us to say yes. And generally what they'd say is you need more information. I'm going to take a big leap here, Howard [Richman] may hit me. But if the information we've given them so far led them to say we can't approve it then they would've already said we can't approve it. Okay? You don't go back and forth like this because the product is not approvable. The question for the agency is the process of putting together the adequacy of the total data set.

(Exhibit E at 3, 5, 6, 10).

121. During the August 21, 2003 Investor Call, Defendants also made statements specifically admitting that their prior statements about Biopure, the Hemopure BLA and the Trauma Clinical Trials were being believed by the marketplace and were causing the price of Biopure stock to increase. For example, the Defendant Moore made the following statements during the August 21, 2003 Investor Call:

> **Thomas A. Moore** - *Biopure - CEO*
>
> In July we completed a public offering raising $17.2 million...In conducting this raise, Chief Financial Officers Ron Richards and I presented to 62 funds in person over a three-week period. This is the most extensive presentation of the company ever, surpassing even the effort behind the IPO launch. **Subsequent share price performance suggests we're beginning to establish an understanding of the exciting future potential for Hemopure** as both a treatment for anemia associated with surgery, and an oxygen therapeutic for use in trauma, surgical ischemias and cancer therapy.

(Exhibit E at 2, emphasis added).

122. Biopure's August 21, 2003 Investor Call was false and misleading to investors about the true information the Company had received from the FDA. First, Defendants misleadingly characterized the Complete Response Letter as a "hybrid" letter when in actuality it was a complete response letter, a fact which had been confirmed by the FDA to Defendant Richman at least twice previously. Second, Defendants falsely stated that the FDA would have 30 days to review a submission from Biopure when in actuality it would have six months to do so, if and when the Company first addressed all 220 deficiencies set forth in the Complete Response Letter. Third, Defendant Moore's statements that the FDA had done Biopure a "big favor" and had "made a commitment to give us an action letter 30 days after we provide our response to their questions" had no basis in fact, were inconsistent with the FDA's prior communications to the Company, and contradicted the six month period to which the FDA was actually entitled in reviewing any future resubmission. Fourth, Defendants falsely stated that Biopure was "in good shape" to address the deficiencies, questions, and concerns in the Complete Response Letter when in actuality they were so numerous and substantial that the Company could not possibly respond to them for years, if ever. In fact, Defendants refused to provide the actual number

of questions in the Complete Response Letter - - 220 in total - - and misleadingly represented as being "substantive" the far lesser number of "50" questions. Fifth, Defendants further misled investors by optimistically describing the likelihood of FDA approval for Hemopure when in actuality there were major obstacles preventing such approval, including the deficiencies, concerns, and questions set forth in both July 30, 2003 letters (including the Complete Response Letter); the clinical hold which FDA had twice refused to lift, and concerns that FDA had discussed with the Company during telephone calls. Finally, Defendants misleadingly discussed the Trauma Clinical Trials while failing to disclose the FDA clinical hold.

123. On August 21, 2003, Biopure's stock closed at $8.25 per share.

124. On or about August 22, 2003, Biopure filed a Form S-3 registration statement and prospectus with the SEC for the sale of common stock and warrants for the purchase of common stock by selling security holders ("August 2003 Offering Documents"). Defendant Moore substantially participated in the drafting, review, and/or approval of the August 2003 Offering Documents, which he signed, and Defendant Richman reviewed their disclosures concerning the regulatory status of Biopure's FDA submissions.

125. In the August 2003 Offering Documents, Biopure did not state that the letter it had received on July 30, 2003 was a "complete response letter." Additionally, the Company made, *inter alia*, the following statement:

> We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication
>
> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its perioperative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's

> indications. To do so, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully. ...

126. Biopure's August 2003 Offering Documents were false and misleading to investors about the true information the Company had received from the FDA. First, the August 2003 Offering Documents failed to disclose, among other things, that the July 30, 2003 letter the Company received from the FDA was a "complete response letter." Second, the August 2003 Offering Documents failed to disclose the clinical hold on the Trauma Clinical Trials, that the hold was put in place due to safety concerns, and that the FDA had twice refused to lift the hold. Third, the August 2003 Offering Documents misled investors by falsely stating that the indication for Hemopure's perioperative use in orthopedic surgery patients was the "only" indication applied for when in actuality the Company had also sought permission to conduct the Trauma Clinical Trials. Finally, the August 2003 Offering Documents disclosed a future "expectation" to expand Hemopure's indications, design additional trials, and submit those trials for FDA review when, in truth, the Company had already designed additional clinical trials (the Trauma Clinical Trials), submitted their designs to the FDA for review, and received a clinical hold imposed by the FDA.

Biopure's Outside Counsel Confirms the Nature of the Complete Response Letter and that a Six Month Period Would Apply to Any Resubmission by the Company

127. On or about August 26, 2003, at the request of Biopure management, the Company's outside counsel contacted FDA staff members to determine whether the FDA planned to issue a second response letter by August 29, 2003. After that conversation, Biopure's outside counsel informed the Company's General Counsel, as well as

Defendants Moore and Richman, in discussions and via e-mails, that despite the use of some non-standard language and the issuance of the letter 30 days prior to the due date, the letter that Biopure received on July 30, 2003 regarding the Hemopure BLA (the Complete Response Letter) was in fact a "complete response letter" for the Hemopure BLA. Biopure's outside counsel further confirmed to the Company's General Counsel, Defendant Moore, and Defendant Richman that the review cycle had been completed without any approval of Hemopure by the FDA and that the FDA would have six months to review any resubmission by Biopure.

Biopure Continues to Misrepresent the Complete Response Letter, to Withhold Information on the True Status of the Hemopure BLA, and to Conceal the Clinical Hold on the Trauma Clinical Trials In Public Statements and Periodic Reports Filed with the SEC, While Selling Biopure Stock

128. On September 12, 2003, Biopure filed with the SEC a Form 424(b)(3) prospectus (the "September 12, 2003 Prospectus"). In the "Risk Factors" section of the September 2003 Prospectus, the Company stated that the letter it received from the FDA on July 30, 2003 was a "complete response letter." On the next trading day, September 15, 2003, the Company's stock dropped by 6.5% on heavy trading. When asked about this trading activity, Biopure's Director of Corporate Communications attributed the stock movement that day to the disclosure that the Company had received a "complete response letter." In e-mail messages sent to investors, he stated that the reference to the FDA's July 30, 2003 correspondence as a "complete response letter" had been a "mistake" by a "junior lawyer at a law firm" used by the Company.

129. On September 15, 2003 (the next trading day following the filing of the September 12, 2003 Prospectus), Biopure filed with the SEC an amended Form 424(b)(3)

prospectus ("September 15, 2003 Prospectus"). The September 15, 2003 Prospectus omitted the reference to the FDA's July 30, 2003 correspondence being a "complete response letter." Defendant Moore substantially participated in the drafting, review, and/or approval of the September 15, 2003 Prospectus. Defendant Richman reviewed the disclosures contained therein concerning the regulatory status of Biopure's FDA submissions.

130. On or about September 15, 2003, Biopure filed with the SEC a Form 10-Q for the quarter ended July 31, 2003 ("July 2003 10-Q"). Defendant Moore substantially participated in the drafting, review, and/or approval of the July 2003 10-Q, which he signed and with respect to which he certified that the document did not "contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." Defendant Richman reviewed the non-financial reporting sections of the July 2003 10-Q.

131. In the July 2003 10-Q, Biopure did not disclose the nature of the Complete Response Letter. In addition, the Company made the following statement:

> We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication
>
> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its periopoerative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. To do so, we will have to design additional clinical trials, submit the trial designs to FDA for review and complete those trials successfully....
>
> * * *

> We also plan to develop Hemopure for potential use in trauma and other medical applications.

132. Biopure's July 2003 10-Q was false and misleading to investors in several ways about the true information that the Company had received from the FDA. First, the July 2003 10-Q failed to disclose, *inter alia*, that the FDA correspondence received by the Company on July 30, 2003 was in fact a "complete response letter" and that the FDA had instituted a clinical hold barring the Company from conducting the Trauma Clinical Trials. Second, the July 2003 10-Q falsely stated that an indication for Hemopure's perioperative use in orthopedic surgery patients was the "only" indication applied for when in actuality the Company had also sought permission to conduct the Trauma Clinical Trials. Third, the July 2003 10-Q disclosed a future "expectation" to expand Hemopure's indications, design additional trials, and submit those trials for FDA review when, in truth, the Company had already designed additional clinical trials (the Trauma Clinical Trials), submitted their designs to the FDA for review, and received a clinical hold imposed by the FDA.

133. On September 10, 2003 Biopure issued a press release announcing that the Defendant Moore would be making a presentation at the ThinkEquity Partners Growth Conference on September 17, 2003. As reflected in the press release, Defendant Moore's statements at that conference were made available to the investing public. The press release, in relevant part, stated as follows:

> ...Biopure Corporation (BPUR) today announced that company President and CEO Thomas A. Moore will present at the ThinkEquity Partners Growth Conference on Wednesday, September 17, 2003, at 9:30 p.m. PT. The investor conference is being held at The OMNI San Francisco from September 16-17, 2003. A live webcast of the 25-minute presentation will be available online via the Investor Relations section of Biopure's web site at www.biopure.com...An archive of the webcast will be available for at least 4 days following the event.

134. On September 17, 2003, the Defendant Moore, gave a presentation about Biopure, Hemopure, and the Hemopure BLA at the ThinkEquity Partners Growth Conference at the Omni Hotel in San Francisco, California. That conference was attended by securities analysts, investment advisors and other members of the investing public. Attached hereto as Exhibit F is a transcript of Defendant Moore's statements at that conference, which are incorporated herein by reference. This transcript was transcribed by Plaintiffs' counsel's personnel, from an audio tape of the Defendant Moore's presentation, which audio tape is in the possession of Plaintiffs' counsel.

135. As reflected in Exhibit F hereto, at the ThinkEquity Growth Partners Conference, the Defendant Moore said:

> ...From a safety standpoint, our agreement with FDA was that the primary safety endpoint would be based on a peak analysis which was a separate analysis of the data done by an independent and blinded medical panel. That panel concluded that our product was not inferior to red blood cells in respect to overall medical risk. This is not the only way the agency looks at safety but it is the primary safety endpoint.

(Exhibit F at 8).

136. That statement was false, deceptive and misleading in light of the FDA's safety concerns, the clinical hold barring the conduct of the Trauma Clinical Trials, and the Complete Response Letter, all of which Biopure and Defendant Moore failed to disclose to Conference attendees.

137. As reflected in Exhibit F hereto, at the ThinkEquity Growth Partners Conference, the Defendant Moore described in detail the history of Biopure, the status of the Hemopure BLA, the anticipated uses for and market for Hemopure, and the economics for Biopure of producing and selling Hemopure. Defendant Moore's entire presentation at

that conference was false, deceptive and misleading in light of the FDA's safety concerns, the clinical hold barring the conduct of the Trauma Clinical Trials, and the Complete Response Letter, all of which Biopure and Moore failed to disclose at the Conference.

138. On September 18, 2003 Biopure issued a press release announcing that Defendant Moore would be making a presentation at the UBS Global Life Sciences Conference on September 25, 2003. As reflected in the press release, Defendant Moore's statements at that conference were made available to the investing public. The press release, in relevant part, stated as follows:

> ...Biopure Corporation (BPUR) today announced that company President and CEO Thomas A. Moore will present at the UBS Global Life Sciences Conference on Thursday, September 25, 2003, at 12:30 p.m. EDT. The investor conference is being held at The Plaza in New York from September 22-25, 2003. A live webcast of the 25-minute presentation will be available online via the Investor Relations section of Biopure's web site at www.biopure.com...An archive of the webcast will be available for at least 4 days following the event.

139. On September 25, 2003, the Defendant Moore made a presentation before the UBS Global Life Sciences Conference in New York, New York. That conference was attended by securities analysts, investment advisors and other members of the investing public. Attached hereto as Exhibit G is a transcript of Defendant Moore's statements at that conference. This transcript was transcribed by Plaintiffs' counsel's personnel, from an audio tape of the Defendant Moore's presentation, which audio tape is in the possession of Plaintiffs' counsel.

140. As reflected in Exhibit G hereto, at the UBS Global Life Sciences Conference, the Defendant Moore said:

> From a safety standpoint, in our pivotal trial, we agreed before the trial began with the FDA to use as our primary safety

> endpoint something called a [Seep?] study. Which is basically a blinded analysis of all the case report forms by a panel of doctors who would examine each patient, create their own score of adverse events and then rank the product use again on a blinded basis in terms of how safe it was for the patient. After all the patients were rated by at least two blinded doctors, we broke the blind, and compared the accumulative scores between our products and red blood cells and achieved a safety objective which was to confirm that our product was not inferior to red blood cells with respect to overall medical risks.

(Exhibit G at 8).

141. That statement was false, deceptive and misleading in light of the FDA's safety concerns, the clinical hold barring the conduct of the Trauma Clinical Trials, and the Complete Response Letter, all of which Biopure and Moore failed to disclose to Conference attendees.

142. As reflected in Exhibit G hereto, at the UBS Global Life Sciences Conference, the Defendant Moore described in detail the history of Biopure, the status of the Hemopure BLA, the anticipated uses for and market for Hemopure, and the economics for Biopure of producing and selling Hemopure. Moore's entire presentation at that conference was false, deceptive and misleading in light of the FDA's safety concerns, the clinical hold barring the conduct of the Trauma Clinical Trials, and the Complete Response Letter, all of which Biopure and Moore failed to disclose to Conference attendees.

Though Biopure Continued to Withhold the Truth about the Hemopure BLA, the FDA's Safety Concerns about Hemopure, the Clinical Hold on the Trauma Clinical Trials, and the Complete Response Letter, the Effects of the Company's Fraud Begin Affecting Its Stock Price

143. On October 30, 2003, before the stock markets opened, Biopure issued a press release (the "October 30, 2003 Press Release"), the text of which was included in a Form 8-K filed with the SEC ("October 30, 2003 Form 8-K"). Defendant Moore substantially

participated in the drafting, review, and/or approval of the October 30, 2003 Press Release, a copy of which is attached hereto as Exhibit H and incorporated herein by reference.

144. The October 30, 2003 Press Release - while still not disclosing to the marketplace the truth about the status of the Hemopure BLA, the FDA's safety concerns about Hemopure, the clinical hold on the Trauma Clinical Trials, and the existence and significance of the Complete Response Letter - disclosed some of their *consequences*, particularly that the FDA would not be acting on the Hemopure BLA until sometime after June 30, 2004. The October 30, 2003 Press Release also disclosed that the Defendant Richman had left Biopure, though it falsely stated that he "...has left Biopure to pursue other interests." In actuality, he had been terminated.

145. The consequences of the still-undisclosed, adverse, material facts had significant, negative financial implications for Biopure, some of which were disclosed in the October 30, 2003 Press Release itself. Among other things, the October 30, 2003 Press Release stated:

> Biopure Corporation (Nasdaq: BPUR) today announced its plan to respond by June 30, 2004 to the Food and Drug Administration's (FDA) questions regarding its biologic license application (BLA) for Hemopure ® [hemoblogin glutamer - 250 (bovine)]. The company has adjusted its operating plan to reduce expenses and conserve cash while it completes its written response to the FDA.
>
> Biopure applied for FDA approval to market the company's oxygen therapeutic, Hemopure, in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients.
>
> During the past two months the company has had several substantive interactions with the FDA to clarify the agency's questions. Many of Biopure's responses have been completed. However, some require the retrieval of source

> medical documents and/or historical blood transfusion data from clinical trial sites in various countries, which will take several months to complete.

146. In addition, the October 30, 2003 Press Release quotes the Defendant Moore as follows:

> "In the best interests of our shareholders, today we've taken the steps necessary to more efficiently run our business while we complete our comprehensive response to all of the FDA's questions," said Biopure President and CEO Thomas A. Moore. "We view the agency's questions as a 'roadmap' to approval and have set a conservative, achievable target date for our response. We remain enthusiastically committed to commercializing Hemopure in the United States as expeditiously as possible."

147. The October 30, 2003 Press Release, and Moore's above quoted statement in the October 30, 2003 Press Release, were false, deceptive and misleading to investors in numerous ways about the true status of Biopure's continuing, but failing, efforts to gain FDA approval for Hemopure. First, in the October 30, 2003 Press Release, the Defendants continued to conceal from investors that the FDA correspondence which Biopure received on July 30, 2003 was a "complete response letter." Second, the October 30, 2003 Press Release failed to disclose that the June 30, 2004 planned response date was dependent upon the Company's pursuing a much narrower indication than that described in the original Hemopure BLA. In fact, prior to issuing the October 30, 2003 Press Release, the Defendants ignored the advice of outside counsel, who, after reviewing a draft of the release, recommended the inclusion of a disclosure that "[i]n its planned response to FDA, Biopure intends to narrow its focus and seek approval only for anemia in those surgical settings where blood transfusion is not an option." Third, the October 30, 2003 Press Release failed to disclose the FDA's safety concerns, as well as the existence and

significance of the clinical hold imposed by FDA which barred conduct of the Trauma Clinical Trials.

148. The October 30, 2003 Press Release also announced that Biopure would be holding a conference call and webcast on October 30, 2003, at 11:30 am, at which "...Moore will discuss the company's regulatory and operating plans..."

149. On October 30, 2003, the Defendants Biopure, Moore and Richards participated in a telephonic conference call for analysts and institutional investors ("October 30, 2003 Investor Call"). Like the May 22, 2003 Investor Call, analysts and institutional investors could participate in the October 30, 2003 Investor Call, and all members of the investing public could hear the call live and access it thereafter for a period of time. A copy of the transcript of that conference call, prepared by CCBN StreetEvents, for Biopure, is attached hereto as Exhibit I, and incorporated herein by reference.

150. During the October 30, 2003 Investor Call, the Defendants made statements and provided answers to questions about Biopure, the Hemopure BLA, and the Trauma Clinical Trials, which were false, deceptive and misleading because, *inter alia*, they omitted and did not disclose the FDA's safety concerns, the existence and significance of the clinical hold on the Trauma Clinical Trials, and Biopure's receipt of the Complete Response Letter. For example, in the October 30, 2003 Investor Call, Defendant Moore was asked about the use of Hemopure in South Africa and responded as follows:

> Our stretch in South Africa has been very positive from the standpoint that we have had good experience with the patients and developed what we consider **a very good safety record** with the product.

(Exhibit I at 3, emphasis added).

151. As described above, the October 30, 2003 Press Release and the Defendants' statements in the October 30, 2003 Investor Call were false and misleading insofar as, *inter alia*, they did not disclose the FDA's safety concerns, the existence and significance of the clinical hold on the Trauma Clinical Trials, and Biopure's receipt of the Complete Response Letter. However, as also described above, they did disclose significant, material adverse consequences being caused by these things to Biopure and the Hemopure BLA, such as Defendant Richman's departure from the Company and the fact that it would take eight additional months to respond to the FDA's July 30, 2003 correspondence.

152. The market's reaction to the negative - though incomplete - disclosures of the consequences of the still-undisclosed, adverse material facts, in the October 30, 2003 Press Release, was immediate and dramatic. On October 29, 2003, the market price of Biopure stock had closed at $6.05 per share, on trading volume of 250,000 shares. On October 30, 2003, the market price of Biopure stock began trading at $5.00 per share; it traded as low as $2.80 per share; and it closed at $3.68 per share on heavy trading volume of 6,910,000 shares. Hence, the market price of Biopure stock experienced a single-day drop of over 39% on October 30, 2003, in reaction to the October 30, 2003 Press Release.

153. The extremely negative reaction to the disclosures in the October 30, 2003 Press Release is also demonstrated in the October 30, 2003 article in TheStreet.com, attached hereto as Exhibit J.

154. The price of Biopure stock continued to decline after October 30, 2003. On October 31, 2003, Biopure stock closed at $3.46 per share; and on the next trading day, November 3, 2003, Biopure stock closed at $3.20 per share. Hence, in the three trading

days after the October 30, 2003 Press Release, the market price of Biopure declined over 47%, from its close at $6.05 per share on October 29 to its close at $3.20 per share on November 3, 2003. Thereafter, the price of Biopure stock continued to decline. On December 24, 2003, prior to the issuance of a December 24, 2003 press release (which was issued *after* the close of the stock market on December 24, 2003) that is described below, Biopure's stock closed at $2.82 per share. December 24, 2003 is the end of the Class Period.

155. The drop in the price of Biopure's stock which occurred on October 30, 2003, and which continued in the days and weeks following, was caused by the *effects* of the Defendants' undisclosed fraud taking root in the marketplace. Although Defendants still had not disclosed the truth about Biopure, Hemopure, the Hemopure BLA, the FDA's safety concerns about Hemopure, the clinical hold on the Trauma Clinical Trials, and Biopure's receipt of the Complete Response letter, some of the consequences of these undisclosed circumstances were made known to the market beginning on October 30, 2003. For example, Defendants publicly stated on October 30, 2003 that Defendant Richman had left the company; that the FDA would not take action on the Hemopure BLA until June 20, 3004; and that the Company had "adjusted its operating plan to reduce expenses and conserve cash" as worked on responses to the FDA.

Biopure Finally Discloses Publicly, For the First Time, the FDA's Safety Concerns, the Clinical Hold on the Trauma Clinical Trials, the Complete Response Letter, the True Status of the Hemopure BLA, and the Ongoing SEC Investigation

156. On or about December 11, 2003, Biopure issued a press release announcing its financial results for the fiscal year ending October 31, 2003 ("December 11, 2003 Press Release"), the text of which was included in a Form 8-K filed with the SEC ("December 11,

2003 Form 8-K"). Defendant Moore substantially participated in the drafting, review, and/or approval of the December 11, 2003 Press Release. In the December 11, 2003 Press Release, Biopure disclosed for the first time that the correspondence it had received from the FDA on July 30, 2003 (over four months prior) was a "complete response letter." The December 11, 2003 Press Release, however, did not disclose the clinical hold on the Trauma Clinical Trials.

157. The market reacted swiftly to the negative - though still incomplete - disclosures in the December 11, 2003 Press Release and December 11, 2003 Form 10-K. On December 11, 2003, the market price of Biopure stock had closed at $2.89 per share, on trading volume of 68,600 shares. On December 12, 2003 (the next trading day following the December 11, 2003 Press Release and the December 11, 2003 Form 8-K), the market price of Biopure stock began trading at $2.52 per share; it traded as low as $2.50 per share before closing at $2.60 per share on heavy trading volume of 218,600 shares. Hence, the market price of Biopure stock experienced a single-day drop of about 10% on December 12, 2003, in reaction to the December 11, 2003 Press Release and the December 11, 2003.

158. The next trading day, December 15, 2003, began a steady week of additional declines in Biopure's closing stock price, from $2.64 (on December 15, 2003) to $2.51 (on December 16, 2003) to $2.49 (on December 17, 2003) to $2.36 (on December 18, 2003) to $2.34 (on December 19, 2003). Thus, just one week after the December 11, 2003 Press Release and December 11, 2003 Form 8-K, Biopure's stock was down just over 19%.

159. The drop in the price of Biopure's stock which occurred on December 12, 2003, and which continued in the days following, was caused by the disclosures in the

December 11, 2003 Press Release and the *effects* of the Defendants' still-undisclosed fraud taking root in the marketplace. Although Defendants had finally disclosed that the correspondence the Company received from the FDA on July 30, 2003 was a "complete response letter," they still had not disclosed the complete truth about Biopure, Hemopure, the Hemopure BLA, the FDA's safety concerns about Hemopure, and the clinical hold on the Trauma Clinical Trials.

160. On December 24, 2003, after the close of the stock markets, Biopure issued a press release (the "December 24, 2003 Press Release"), the text of which was included in a Form 8-K filed with the SEC ("December 24, 2003 Form 8-K") and a copy of which is attached hereto as Exhibit K and incorporated herein by reference.

161. In the December 24, 2003 Press Release Biopure publicly revealed, *for the first time ever*, the existence of the FDA's clinical hold on the Trauma Clinical Trials, which had been imposed over eight months before. Biopure also disclosed that the Defendants Biopure, Moore and Richman had each received a "Wells Notice" from the SEC, advising that the SEC staff had made a preliminary determination to recommend the filing of a civil enforcement staff action against them.

162. In particular, the December 24, 2003 Press Release stated, in part, as follows:

> CAMBRIDGE, Mass., Dec 24, 2003 ... Biopure Corporation (BLUR) reported that on December 22, 2003, it received a "Wells Notice" from the staff of the Securities and Exchange Commission (SEC) indicating the staff's preliminary decision to recommend that the SEC bring a civil injunctive proceeding against the company.... The company's chief executive officer [the Defendant Moore] and its former senior vice president of Regulatory and Operations [the Defendant Richman] also received Wells Notices.

> ... the notices relate to the company's disclosures concerning its communications with the Food and Drug Administration (FDA) about a trauma study protocol the company submitted to the Agency in March 2003 and about the company's biologics license application (BLA) for Hemopure ® [hemoglobin glutamer - 250 (bovine)]....
>
> Biopure submitted the trauma protocol for a Phase II clinical trial of Hemopure for the treatment of hemorrhagic shock casualties in the hospital setting, where red blood cell transfusions are available....
>
> After the in-hospital trauma protocol was submitted to the FDA...**the Agency placed a clinical hold on the proposed trauma trial due to safety concerns. The FDA referred to a review of adverse event data from the company's Phase III orthopedic surgery trial, which was submitted in the BLA**....(emphasis added)
>
> In May 2003, Biopure responded to the FDA's clinical hold and also filed the response as a BLA amendment because it discussed data previously submitted with the BLA. That amendment resulted in the FDA extending its BLA review period up to 90 days, as previously announced on May 30, 2003.... After the company's responses, the FDA has twice declined to lift the clinical hold, most recently in a letter dated July 30, 2003. This letter is separate from the FDA complete response letter Biopure received on that date in response to its BLA for orthopedic surgery. The questions in the FDA's trauma letter were the same as some of the questions in the BLA complete response letter....

(emphasis added)

163. The December 24, 2003 Press Release informed the investing public, for the first time, about the FDA's safety concerns regarding Hemopure as a result of adverse event data from Biopure's Phase III clinical trial for its Hemopure BLA; the fact that, in light of those safety concerns, the FDA had placed a clinical hold on the Trauma Clinical Trials, which had first been communicated to the Defendants by the FDA on April 9, 2003; the serious impact those safety concerns had and were continuing to have on the prospects

of the Hemopure BLA being approved by the FDA; and the delays those safety concerns would cause in the FDA's decision regarding the Hemopure BLA.

164. The December 24, 2003 Press Release informed the investing public, for the first time, that due to the FDA's safety concerns regarding Hemopure as a result of adverse event data from Biopure's Phase III clinical trial for its Hemopure BLA, the FDA had, on April 9, 2003, placed a clinical hold on the Trauma Clinical Trials.

165. The December 24, 2003 Press Release also informed the investing public, for the first time, that the Defendants' public statements during the Class Period regarding Biopure, the Hemopure BLA, and the Trauma Clinical Trials had been false, deceptive and misleading; that the SEC was investigating those false and deceptive statements and that the SEC staff had decided to recommend that the SEC bring an enforcement action against the Defendants Biopure, Moore and Richman.

166. These first-time disclosures had a significant negative effect on the Company's stock price. On the very next trading day, Friday, December 26, 2003, Biopure's stock closed down 13.83% at $2.43. On Monday, December 29, 2003, Biopure's stock closed down again at $2.33, which represented a 17.38% decrease from the closing price on December 24, 2003.

167. The drop in Biopure's stock price from December 11, 2003 to December 24, 2003 and then from December 26, 2003 to December 29, 2003 was caused by the partial disclosures of the fraud alleged herein on December 11, 2003 and December 24, 2003. The price drops in Biopure's stock from October 30, 2003 to December 10, 2003, were caused by the market's reaction to the *effects* on the Company of the then-still-undisclosed fraud.

168. On January 29, 2004, Biopure filed its Annual Report for its fiscal year ended October 31, 2003 with the SEC on Form 10-K/A (hereinafter the "2003 10-K"). The 2003 10-K was signed by all of the Individual Defendants except Richman. In the 2003 10-K, the Defendants disclosed some additional adverse material information concerning the SEC's investigation and Biopure's communications with the FDA during the Class Period. Specifically, the Defendants disclosed the following in the 2003 10-K:

> **13. Litigation and Subsequent Events**
>
> *SEC Investigation.* During the fourth quarter of fiscal 2003, the Company was notified of a confidential investigation by the Securities and Exchange Commission (SEC). On December 22, 2003, the Company, its Chief Executive Officer and its former Senior Vice President, Regulatory and Operations received "Wells Notices" from the staff of the SEC stating the staff's preliminary determination to recommend that the SEC bring a civil injunctive proceeding against the Company and the individuals. Biopure and the individuals responded in writing to the notices on January 9, 2004. The staff is continuing to gather information.
>
> Biopure believes the notices relate to Company disclosures concerning communications with the FDA about a clinical hold imposed on a clinical study protocol the Company submitted to the agency in March 2003 and the status of the Company's BLA. In March 2003, the Company filed a proposed protocol for a Phase II clinical trial in trauma patients in a hospital setting. The FDA put the protocol and its related investigational new drug application (IND) on "clinical hold," meaning the trial could not begin as proposed. The FDA cited safety concerns based on a preliminary review of data from the Company's trial in patients undergoing orthopedic surgery. After the Company responded in two written submissions, the clinical hold was reasserted twice in writing, most recently on July 30, 2003. The Company did not disclose the clinical hold because the Company did not consider correspondence with the agency about data interpretation in the development of a protocol to be material, notwithstanding the references to data in the BLA. The staff's investigation also concerns the Company's disclosures concerning the FDA's review of the BLA, after receipt of the complete response letter dated July

> 30, 2003. The Company has been cooperating throughout the investigation with the SEC staff. At this time, the Company cannot estimate what impact, if any, this inquiry may have on its financial position or results of operations.

169. On April 30, 2004, Biopure issued a press release ("April 30, 2004 Press Release") in which it disclosed that on April 29, 2004, the SEC staff had issued four *additional* Wells Notices, indicating that the SEC staff was considering recommending that the SEC *also* bring civil actions against the Defendants Sanders, Crout and Rausch, and Biopure General Counsel, Jane Kober, for violations of the federal securities laws. The April 30, 2004 Press Release read, in part, as follows:

> CAMBRIDGE, Mass., Apr 30, 2004...Biopure Corporation (BPUR) reported today that on April 29, 2004, the U.S. Securities and Exchange Commission (SEC) issued additional "Wells Notices" to four individuals concerning matters disclosed in Biopure's press release dated December 24, 2003. The notices indicate that the SEC staff may recommend that the Commission bring a civil action against Biopure's non-executive Chairman Dr. Charles A. Sanders, former Board Member Dr. J. Richard Crout, Chief Technology Officer and Board Member Carl W. Rausch, and General Counsel Jane Kober for possible violations of federal securities laws. The notices afford the individuals an opportunity to respond in writing before the SEC staff formally decides what action, if any, to recommend.
>
> Biopure will continue to cooperate with the SEC staff in the matters investigated. As previously disclosed, Biopure believes that the SEC investigation relates to the company's disclosures concerning its communications with the U.S. Food and Drug Administration (FDA) about a proposed trauma study protocol the company submitted to the FDA in March 2003 and about the company's biologics license application (BLA) for Hemopure®...

The Defendants Biopure and Rausch Sold Millions of Dollars of Biopure Stock During the Class Period, While In Possession of Material, Adverse, Non-Public Information Regarding Biopure

170. While Defendants engaged in the fraudulent and unlawful conduct described herein, and while in possession of material, adverse, nonpublic information regarding the Company described herein, Defendants Biopure and Rausch made millions of dollars through transactions involving Biopure stock during the Class Period.

171. On or about April 16, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure realized $3,032,000 in net proceeds from the sale of shares and warrants.

172. On May 2, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 882,353 shares of Biopure common stock for $3.57 per share, for a total of $3,150,000. Those shares were registered with the SEC under a shelf registration.

173. On May 6, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 833,334 shares of Biopure common stock for $3.60 per share, for a total of $3,000,000. Those shares were registered with the SEC under a shelf registration.

174. In May and June 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 707,060 shares of Biopure common stock at an average price of $5.56 per share, for a total of $3,839,000. Those shares were registered with the SEC under a shelf registration.

175. On or about July 23, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 3,083,000 shares of Biopure common stock for $5.58 per share, for a total of $17,203,140. Those shares were registered with the SEC under a shelf registration.

176. Between August 1, 2003 and September 15, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 802,188 shares of Biopure common stock at an average price of $7.55 per share, for a total of $6,003,000.

177. In September 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 522,193 shares of Biopure common stock at a price of $4.84 per share, for a total of $2,527,000.

178. Throughout the Class Period, Biopure had sales of up to $10,000,000 of common stock issued from time to time by the standby equity distribution agreement with CMI.

179. During the fiscal year ended October 31, 2003, approximately eight months of which falls within the Class Period, warrants to purchase 712,141 shares of Biopure's common stock were exercised at an average exercise price of $4.52 per share, generating $3,200,000 in net proceeds in the process.

180. During the Class Period, while in possession of the non-public material adverse information regarding the Company, the Defendant Rausch sold a total of 276,574 shares of Biopure, for approximately $1,596,000. Those shares constituted 33.7% of the Biopure shares owned by Rausch at the beginning of the Class Period. Specifically, Rausch sold the following numbers of Biopure shares on the following dates:

DATE BIOPURE SHARES SOLD BY RAUSCH	NUMBER OF SHARES SOLD BY RAUSCH	PRICE PER SHARE	TOTAL RECEIVED BY RAUSCH
4/15/03	30,000	$3.13	$93,900
6/5/03	2,000	$6.06 - $6.07	$12,000

DATE BIOPURE SHARES SOLD BY RAUSCH	NUMBER OF SHARES SOLD BY RAUSCH	PRICE PER SHARE	TOTAL RECEIVED BY RAUSCH
6/24/03	3,000	$5.58 - $5.698	$17,000
6/25/03	2,700	$5.80 - $5.97	$16,000
6/26/03	34,374	$5.80 - $5.90	$201,000
6/27/03	20,000	$5.95 - $6.00	$120,000
6/30/03	5,000	$6.14 - $6.16	$31,000
8/5/03	10,000	$7.50 - $7.53	$75,000
8/6/03	2,000	$7.50 - $7.54	$15,000
8/7/03	8,000	$7.00	$56,000
8/8/03	10,000	$7.05 - $7.28	$72,000
8/12/03	10,000	$7.00 - $7.15	$71,000
8/13/03	9,500	$7.02 - $7.15	$67,000
8/28/03	100,000	$7.50	$750,000
TOTALS	246,574		$1,596,900

Plaintiffs' Purchases of Biopure Stock During the Class Period

181. Plaintiff Erickson purchased a total of 75,000 shares of Biopure common stock during the Class Period, on the following dates:

DATE BIOPURE SHARES PURCHASED	NUMBER OF SHARES PURCHASED
05/16/03	11,600
05/16/03	500
05/16/03	300
05/16/03	2,500
05/16/03	100
05/16/03	100
05/16/03	1,000
05/16/03	5,000
05/16/03	100
05/16/03	200
05/16/03	2,700
05/16/03	100
05/16/03	800
05/29/03	5,000
05/29/03	5,000
05/29/03	5,000
05/29/03	10,000
05/29/03	10,000
05/29/03	10,000
05/30/03	5,000
TOTAL	75,000

182. Plaintiff Gottlieb purchased the following number of shares of Biopure common stock on the following dates:

DATE BIOPURE SHARES PURCHASED	NUMBER OF SHARES PURCHASED
4/17/03	3,000
4/29/03	2,500
5/19/03	2,000
5/20/03	1,400
6/23/03	1,000
8/22/03	3,000
8/25/03	1,000
8/26/03	500
TOTAL	14,400

183. Plaintiff Bittman purchased 100 shares of Biopure common stock on June 5, 2003 and 420 shares of Biopure common stock on August 26, 2003.

184. Plaintiff Esposito purchased 600 shares of Biopure common stock on August 12, 2003 and 600 shares of Biopure common stock on August 21, 2003.

SCIENTER ALLEGATIONS

185. The Defendants' conduct, as detailed herein, in issuing false, deceptive and misleading statements to the investing public about Biopure, Hemopure, the Hemopure BLA, the Trauma Clinical Trials, the FDA's safety concerns about Hemopure, the clinical hold, and the Complete Response Letter, was conducted by the Defendants knowingly, purposely, intentionally and recklessly, with the full knowledge that their conduct would, and with the full intention that their conduct would, mislead, deceive and act as a fraud upon the investing public.

186. In 2002, the Defendants Biopure and Rausch were named as defendants in a federal securities fraud class action entitled, *Thomas H. Meyer, et als. v. Biopure*

Corporation and Carl W. Rausch, in the United States District Court for the District of Massachusetts (Civil Action No. 02-10194-EFH). In that action the Plaintiffs alleged that the Defendants had committed securities fraud by failing to disclose defects and deficiencies in the clinical trials conducted for Hemopure. Judge Harrington of this Court, in an Opinion reported at 221 F.Supp. 2d 195 (D. Mass. 2002), dismissed that complaint. In so doing, Judge Harrington, in language extraordinarily relevant to, and indeed, ironic in light of, the facts in this action, said:

> Plaintiffs also plead no basis for inferring that it is highly likely that these alleged omissions were either intentional or highly reckless...**this is not a situation where the facts omitted from the press release are so clearly important that the fact of non-disclosure alone gives rise to a strong inference of scienter, since plaintiffs do not suggest that the "missing" data would show that Hemopure was unsafe**...

222 F. Supp. 2d at 207 (emphasis added).

187. Hence we see that even beyond the obvious materiality of the FDA's safety concerns and the Complete Response Letter, the Defendants knew full well, from Judge Harrington's decision in the *Meyer v. Biopure* case, that facts which "...would show that Hemopure was unsafe..." Id., were not only material but "...so clearly important that the fact of non-disclosure alone gives rise to a strong inference of scienter..." Id. The Defendants' failure to disclose the FDA's safety concerns, the clinical hold on the Trauma Clinical Trials prompted by those safety concerns and the Complete Response Letter, under these circumstances, creates the strongest possible inference of *scienter*.

188. *Scienter* is also apparent here from the fact that the SEC reached the conclusion, based upon the facts alleged in this Complaint and the SEC Complaint,

incorporated herein by reference, that the Defendants Biopure, Moore and Richman acted with *scienter* in violation of the federal securities laws due to their false and misleading statements regarding, and their failure to disclose the truth about, Biopure, Hemopure, the Hemopure BLA, the Trauma Clinical Trials, the FDA's safety concerns about Hemopure, the clinical hold, and the Complete Response Letter during the Class Period. In light of that conclusion by the SEC, the SEC filed the SEC Action on September 14, 2005.

189. *Scienter* is also apparent here from the fact that after the SEC staff's receipt of the responses by the Defendants Biopure, Moore and Richman to the SEC staff's Wells Notices, the SEC staff responded on April 29, 2004 by issuing additional Wells Notices (advising that the SEC staff may recommend to the SEC that it also bring action against the Defendants Sanders, Rausch and Crout, as well as Biopure's general counsel, Jane Kober, for violations of the federal securities laws due to their failure to disclose the FDA's Safety Concerns during the Class Period).

190. The Defendants' *scienter* is also apparent from the highly significant and material changes which the Defendants made to the False and Deceptive Statement Regarding "*If We Fail To Obtain FDA Approval,*" after the SEC began its investigation of the Defendants during Biopure's fiscal quarter ended October 31, 2003. Specifically, in the Form S-3 registration statement filed with the SEC on August 22, 2003, which was signed by all of the Individual Defendants, except Richman, the Defendants replaced the False and Deceptive Statement Regarding "*If We Fail To Obtain FDA Approval,*" with the following statement:

> ***If We Fail to Obtain FDA Approval, We Cannot Market Hemopure in the United States***

> We will not be able to market Hemopure in the United States unless and until we receive FDA approval. We filed an application for approval with the FDA, and the application was accepted for review on October 1, 2002. The FDA advised us that it would complete its review and take action on the application by August 29, 2003. By letter dated July 30, 2003, the FDA gave us comments on the application, stating that it had completed its review. We are working on our responses. However, the FDA could find that our responses do not address its issues adequately and could require additional data or even further clinical trials ...prior to approval of Hemopure. Trials are expensive and time-consuming and we may not have the financial resources to fund such trials. Despite all of our efforts, the FDA could refuse to grant a marketing authorization.

191. Significantly, this new version of this "risk disclosure," while still false, deceptive and misleading because the Defendants continued to fail to disclose in it the FDA's safety concerns, the clinical hold and the Complete Response Letter, no longer contained the Defendants' false and deceptive statement: **"We believe that our completed pivotal Phase III clinical trials are consistent with the FDA's most recent guidance on...safety endpoints required for approval of products such as Hemopure for use in surgical indications..."** which the Defendants had repeatedly, falsely stated prior to August 22, 2003.

192. Another indicia of the Defendants' *scienter* is seen from the disparity between the Defendants' evasive description of the status of the Trauma Clinical Trials, and their straightforward description of the status of clinical trials of one of their potential competitors. As detailed herein, due to the FDA's safety concerns, the FDA placed the Trauma Clinical Trials on clinical hold on April 9, 2003, immediately after Biopure submitted a Phase II protocol for those trials. Thereafter, the FDA twice refused to lift that clinical hold, the last such action having occurred on July 30, 2003 via the July 30,

2003 Clinical Trials Letter. Nevertheless, throughout the Class Period, the Defendants, while repeatedly discussing the Trauma Clinical Trials, fastidiously avoided disclosing the fact that the FDA had placed the Trauma Clinical Trials on a clinical hold. In contrast, at his presentation at the above described ThinkEquity Conference on September 17, 2003, when describing the research efforts of one of Biopure's potential competitors, the Defendant Moore had no hesitation in saying:

> **"Hemosol is now on a clinical hold. It is not clear whether it will be able to resume."**

That exact same statement would have fully, accurately and non-deceptively described the status of the Hemopure Trauma Clinical Trials throughout the Class Period, and the Defendants could have, and should have, so disclosed the status of the Hemopure Trauma Clinical Trials, during the Class Period. The fact that the Defendants made this straightforward statement regarding the status of the clinical trials for their competitor's product, but did not do so regarding the Hemopure Trauma Clinical Trials, demonstrates the Defendants' *scienter* in purposely and intentionally failing to do so.

193. The Defendants' *scienter* is also seen from their extraordinary motive to deceive the investing public regarding the prospects of Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials. As the Defendants repeatedly disclosed in their SEC filings, Biopure was dependent for its continued operations and financial survival on its ability to periodically raise money from the investing public, through the sale of shares of Biopure and warrants to buy shares of Biopure. As detailed above, Biopure raised millions of dollars during the Class Period by selling its shares to investors. Biopure's ability to continue to sell its shares would have been severely compromised by the Defendants' disclosure of the FDA's safety concerns, the

clinical hold in place on the Hemopure BLA, and the FDA's transmission of the Complete Response Letter.

194. The Defendants' *scienter* is also evidenced by the fact that when the September 12, 2003 Prospectus correctly identified the correspondence Biopure received from the FDA on July 30, 2003 as being a "complete response letter," and when the Company's stock then dropped 6.5% the next trading day on heavy trading volume, Biopure's Director of Corporate Communications intentionally, falsely, and deceptively said that the reference to the July 30, 2003 correspondence as a "complete response letter" had been a "mistake" by a "junior lawyer at a law firm" used by the Company. The Defendants' *scienter* is further demonstrated by the filing, on the next trading day, of the September 15, 2003 Prospectus, which omitted the reference to the FDA's July 30, 2003 correspondence being a "complete response letter."

195. The Defendants' *scienter* is also seen by the sales by Biopure and Rausch of hundreds of thousands of shares of Biopure stock during the Class Period, as detailed herein.

INAPPLICABILITY OF THE EXCHANGE ACT'S THE SAFE HARBOR PROVISIONS FOR FORWARD-LOOKING STATEMENTS

196. The provisions of Section 21E of the Exchange Act, which provide, under specified circumstances, a safe harbor from liability under the Exchange Act for "forward-looking statements," are not applicable to the claims asserted herein against the Defendants.

197. Section 21E(c)(1)(B) provides that the safe harbor provisions of Section 21E do not apply if the plaintiffs prove that the forward-looking statement:

> (i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or
>
> (ii) if made by a business entity; was
>
> > (I) made by or with the approval of an executive officer of that entity; and
> >
> > (II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

198. As demonstrated in detail herein, the Individual Defendants and Biopure had actual knowledge of the FDA's safety concerns and the clinical hold on the Trauma Clinical Trials throughout the Class Period and actual knowledge of the Complete Response Letter as of July 30, 2003. Hence, the false, misleading and deceptive statements of the Individual Defendants were made by those Individual Defendants "with actual knowledge by [those] person[s] that the statement[s were] false or misleading." Likewise, the false, misleading and deceptive statements by Biopure were "made by or with the approval of [one or more] executive officer[s] of..." Biopure, and that the executive officers of Biopure who made or approved those statements had actual knowledge "that the statement[s were] false or misleading."

199. Accordingly, the exemption provisions of Section 21E do not apply to and will not exempt the Defendants from liability for the securities fraud claims asserted against them in this action.

200. Furthermore the Defendants' statements of their opinions, projections and forecasts concerning Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials, during the Class Period, as detailed herein, were lacking in a reasonable basis at

all times and did not, in fact, constitute their truly believed opinions, projections and forecasts concerning Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials, during the Class Period.

201. Furthermore, a significant number of the Defendants' false, deceptive and misleading statements, as detailed herein, were not " forward looking statements," but in fact were statements (or misstatements) of existing fact and hence the exemption provisions of Section 21E do not apply to and will not exempt the Defendants from liability for the securities fraud claims asserted against them in this action.

CLASS ACTION ALLEGATIONS

202. The Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class (the "Class") consisting of all persons or entities ("Class Members") who acquired shares of Biopure common stock from April 9, 2003 through December 24, 2003, (the "Class Period") and who were damaged thereby. Excluded from the Class are Defendants; members of the individual defendant's immediate family; any past or present director, officer, subsidiary, or affiliate of Biopure; any entity in which any excluded person or entity has a controlling interest; and their legal representatives, heirs, successors and assigns.

203. The Plaintiffs also bring this action on behalf of a subset of the Class (the "Sub-Class") consisting of all persons or entities who acquired shares of Biopure common stock contemporaneously with the sales of Biopure stock by the Defendants Biopure and Rausch during the Class Period and who were damaged thereby. Excluded from the Sub-Class are Defendants; members of the individual defendant's immediate family; any past or present director, officer, subsidiary, or affiliate of Biopure; any entity in which any

excluded person or entity has a controlling interest; and their legal representatives, heirs, successors and assigns.

204. The members of the Class and Sub-Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are thousands of members of the Class and Sub-Class located throughout the United States. Throughout the Class Period, Biopure common stock was actively traded in an efficient market on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Biopure and/or its transfer agent and may be notified of the pendency of this action by mail and publication, using forms of notice similar to those customarily used in securities class actions.

205. Plaintiffs' claims are typical of the claims of other members of the Class as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

206. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

207. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. Whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

b. Whether Defendants participated in and pursued the illegal course of conduct complained of herein;

c. Whether statements disseminated to the investing public during the Class Period were misrepresentations and/or suffered from omissions of material information as alleged herein;

d. Whether, when defendants Biopure and Rausch sold shares of Biopure during the Class Period, they were in possession of material, adverse, non-public information regarding Biopure, including in particular, *inter alia*, information regarding the FDA's safety concerns, the clinical hold on the Trauma Clinical Trials, and Biopure's receipt of the Complete Response Letter;

e. Whether the market price of Biopure common stock during the Class Period was artificially inflated due to the material misrepresentations and omissions complained of herein; and

f. The extent to which the members of the Class have sustained damages and the proper measure of damages.

208. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. As the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigations make it impossible for members of the Class individually to seek redress for the wrongs done to them. There will be no difficulty in the management of this suit as a class action.

COUNT I

AGAINST ALL DEFENDANTS FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE10b-5 PROMULGATED THEREUNDER

209. Plaintiffs repeat and reallege each and every paragraph set forth above.

210. During the Class Period, Defendants, and each of them, carried out a plan, scheme and course of conduct that was intended to and/or did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate the market price of Biopure common stock; and (iii) cause Plaintiffs and other members of the Class to buy Biopure stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, and each of them, took the actions set forth herein.

211. These Defendants: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon the buyers of Biopure common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

212. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly.

213. As a result of the Defendants' dissemination of the deceptive and misleading information regarding Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials, and their failure to disclose the FDA's safety concerns regarding Hemopure, the clinical hold on the Trauma Clinical Trials, and the Complete Response Letter, as set forth above, the market price of Biopure's common stock was artificially inflated during the Class

Period. In ignorance of the fact that the market price of Biopure's shares were artificially inflated, and relying upon the integrity of the efficient market in which Biopure common stock trades, and/or on the absence of material information that was known to and/or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class bought Biopure common stock during the Class Period at artificially inflated prices and were damaged thereby when the price of Biopure stock thereafter declined due to the Defendants' fraudulent conduct.

214. At the time of said misrepresentations and omissions, Plaintiffs and the other members of the Class were ignorant of the omitted material facts and believed Defendants' statements regarding Biopure to be completely truthful, candid and not deceptive or misleading or suffering from omissions of material facts. Had Plaintiffs and the other members of the Class known of the omitted material facts, Plaintiffs and the other members of the Class would not have bought their Biopure common stock during the Class Period, or, if they had bought such stock during the Class Period, they would not have done so at the artificially inflated prices which they paid for their Biopure common stock which they bought during the Class Period and they would not have suffered losses when the price of Biopure stock thereafter declined due to the Defendants' fraudulent conduct.

215. By virtue of the foregoing, each of the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

216. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Biopure common stock during the Class Period.

COUNT II

AGAINST THE INDIVIDUAL DEFENDANTS PURSUANT TO SECTION 20(a) OF THE EXCHANGE ACT

217. Plaintiffs repeat and reallege each and every paragraph set forth above.

218. This claim is asserted against the Individual Defendants pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. §78t(a).

219. During the entire Class Period, the Defendants Moore, Rausch, Richards, Sanders and Crout were "controlling persons" of Defendant Biopure, within the meaning of Section 20(a) of the Exchange Act.

220. During the portion of the Class Period from April 9, 2003, to the date he resigned or was terminated as Biopure's Senior Vice President of Regulatory Affairs and Operations, which was sometime prior to October 30, 2003, the Defendant Richman was a "controlling person" of Defendant Biopure, within the meaning of Section 20(a) of the Exchange Act.

221. The Individual Defendants were "controlling persons" of Biopure because, due to the officer and/or director positions they held with Biopure, they had the influence and power over Biopure to cause, and they did cause, Biopure to engage in the wrongful conduct complained of herein, and because they had the power to have prevented Biopure from engaging in the unlawful conduct alleged herein, but they purposely, intentionally and recklessly did not use that power to do so.

222. As set forth above in Count I, Biopure violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by its acts and omissions as alleged in this Complaint. By virtue of their status as "controlling persons" of Biopure, the Individual Defendants are liable, to the same extent as is Biopure, for Biopure's violations of Section

10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, pursuant to Section 20(a) of the Exchange Act.

COUNT III

AGAINST THE DEFENDANTS BIOPURE AND RAUSCH PURSUANT TO SECTION 20A OF THE EXCHANGE ACT

223. Plaintiffs repeat and reallege each and every paragraph set forth above.

224. This claim is asserted against the Defendants Biopure and Rausch pursuant to Section 20A of the Exchange Act. The Defendants Biopure and Rausch are hereinafter sometimes referred to collectively as the "Section 20A Defendants."

225. During the Class Period, the Defendants Biopure and Rausch, while in possession of the non-public material adverse information regarding the Company, sold millions of dollars of shares of the Company. Because the Section 20A Defendants possessed material adverse information about the Company which was not known to the investing public, including the members of the Sub-Class, Section 20A Defendants sold their shares of the Company at artificially inflated prices and the members of the Sub-Class, who purchased shares of the Company contemporaneously with the sales by the Section 20A Defendants, paid artificially inflated prices for those shares of the Company, and were damaged thereby.

226. Pursuant to Section 20A of the Exchange Act, the Defendants Biopure and Rausch are liable to the members of the Sub-Class for the difference between the inflated prices at which they sold their shares of the Company during the Class Period, and the prices at which those shares would have sold had the investing public known the material adverse information about Biopure which was known to the Section 20A Defendants.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Class, pray for judgment as follows:

A. Declaring this action to be a class action properly maintained pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure;

B. Finding that the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by their acts and omissions as alleged in this Complaint;

C. Finding that the Defendants Biopure and Rausch violated Section 20A of the Exchange Act by their acts and omissions as alleged in this Complaint;

D. Awarding Plaintiffs and the members of the Class and the Sub-Class damages, together with interest thereon;

E. Awarding Plaintiffs and other members of the Class and the Sub-Class their costs and expenses of this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

F. Awarding Plaintiffs and other members of the Class and the Sub-Class such other and further relief as may be just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury.

By the attorneys for the Plaintiffs and the Class and the Sub-Class,

SHAPIRO HABER & URMY LLP

By: **/s/ Edward F. Haber**

Edward F. Haber BBO No. 215620
Matthew L. Tuccillo BBO No. 643336
Shapiro Haber & Urmy LLP
53 State Street, 37th Fl.
Boston, MA 02109
(617) 439-3939

Jules Brody
Howard T. Longman
Stull Stull & Brody
6 East 45th Street
New York, NY 10017
(212) 687-7230

Dated: March 28, 2006